The Global Financial Crisis:

A ROADBLOCK IN THE TRANSLATIONAL SCIENCE HIGHWAY?

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It is well recognized that the highway that connects the elements of the clinical and translational sciences—basic research, clinical research, and the delivery of care to the community—is filled with a variety of obstructions that impede the bidirectional flow of information and technology. Others are far more insidious and often go unrecognized by many members of the translational medicine community. One such roadblock is the

adverse affects on technology transfer that have come about as a result of the global financial crisis.

Historically, universities and academic medical centers have taken a variety of approaches to capitalize on their intellectual property. Many universities license intellectual property to a biotechnology company that in turn files the necessary

patent applications. The license agreement often provides some up-front payments. More meaningful funds come from royalty payments once the product is actually sold.

Alternatively, some universities have spun-out companies to develop the intellectual property rather than out-licensing the technology. These universities have used their internal resources to fund the formation of a new company or in some situations have collaborated with other local institutions to form a biotechnology “incubator” that can provide a turn-key operation for new companies. While the university faces up-front costs, the university and the inventor often receive substantive financial rewards earlier in the process, especially when the start-up company is sold to a larger company or is taken public based on results of Phase I or Phase II studies. Regardless of the strategy that is used to commercialize intellectual property, the ability of any university to pursue entrepreneurial efforts during a global financial crisis becomes incredibly challenging.

Although the global markets have clearly impacted our ability to move new drugs and devices from discovery to implementation, they have also had a profound effect on the biotechnology industry and as a result on our ability to translate discoveries to the clinical arena. The economic collapse, for example, has all but eliminated the opportunity for privately held biotechnology companies to raise money through a public offering of stock or an IPO. As a result, these companies are rapidly expending all of their existing capital and it is estimated that 50 percent of them will be out of business by the beginning of 2010. Because existing biotechnology companies

cannot raise capital through a public offering, the venture capital companies that have funded them face the difficult choice of allowing them to close or spending their own precious dollars to continue to support them until the economy turns around or their early clinical studies are completed. This limits the ability of the existing venture capital companies to fund the evaluation of new discoveries as they must use their capital for the support of their current portfolio.

While university- or state-sponsored biotechnology incubators once played an important role in supporting young companies before they acquired venture capital financing, the budget woes of most state governments and the precipitous fall in the value of university endowments have limited the ability of these entities

to support discovery. Surprisingly, even the large pharmaceutical companies have turned their backs on new discovery in academia. This is illustrated by the fact that Pfizer spent billions of dollars to buy Wyeth, a company with a limited drug

pipeline, rather than investing those same dollars in potentially exciting biotechnology companies.

Because of these challenges new discoveries may sit on the shelf in academic laboratories rather than being evaluated in clinical trials. Similarly, exciting new drugs also sit on the shelves of underfunded biotechnology companies—drugs that may well fall by the wayside if these companies fail over the next 12 to 24 months. Not only does this impede the translation of these discoveries to new diagnostic and therapeutic products, it also lessens the value of the intellectual property as the patent clock ticks. Eventually the patent life of these drugs will be expended and so, too, their commercial value.

So how does an individual investigator or an academic technology transfer office move discoveries into the drug or device development pathway during these challenging times? Could changes in the patent laws provide an opportunity to extend the patent life of potentially life-saving drugs that have not been developed because of the impact of the global fiscal crisis? Should the Obama Administration set aside stimulus dollars to support drug discovery in the academic or biotechnology arenas? Unfortunately, we are scientists and often entrepreneurs, but not economists. Therefore, in forthcoming issues we will discuss these issues with nationally respected leaders in venture capital, technology transfer, finance, economics, and biotechnology to learn what steps we can take as a community of translational medicine scholars to ensure that traffic keeps flowing on the translational highway. **CTS**

I was astonished to learn just how profound an effect the current crisis has had on the biotechnology industry and as a result on our ability to translate discoveries to the clinical arena.—Arthur M. Feldman, MD, PhD

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