ENATION

MEETING



FINANCING INNOVATION

Government-University-Industry Research Roundtable February 24-25, 2014

s tough economic times continue, federal and state agencies, universities, and the private sector are examining how best to fund research in the sciences, engineering, and technology despite financial constraints. At this GUIRR meeting, members considered new financing models and mechanisms designed to more efficiently convert the nation's research assets into economic assets, thereby increasing the nation's overall competitiveness.

The keynote address was given by **Tom Kalil**, Deputy Director for Technology and Innovation at the White House Office of Science and Technology Policy (OSTP) on February 24. Kalil opened by raising the question of whether it is possible to develop a taxonomy of areas in which the U.S. should be experimenting with new approaches to financing innovation. This question, he said, is premised on two ideas in tension. First, there are areas where markets fail in terms of supporting innovation due to externalities, public goods, and market asymmetries. Second, and in contrast, governments are not always able to maximize the public welfare with regard to investment in innovation.

This is especially true where the benefits are particularly concentrated while the costs are quite diffuse, Kalil explained.

As examples of less-than-ideal market outcomes, Kalil pointed to areas in which angel and venture capitalists are reluctant to invest. He noted that certain sectors of innovation that are high-risk and high-reward but which have a longer time to exit, such as energy technologies and medical devices, are likely to be avoided by venture capitalists. In addition, Kalil explained that particular stages of the innovation process, namely the "valley of death" (after government has stopped funding basic research but before it is possible to demonstrate high-volume, cost-effective repeatable manufacturing) are challenging to fund.

Kalil also discussed the likelihood that innovations that benefit poor people would go unfunded. For example, investing in a vaccine that will be targeted to people living on \$1 to \$2 per day may be a difficult thing for a pharmaceutical company to justify to its shareholders. One way to solve this is through an advance market commitment; for example, five countries and the Gates Foundation made a

THE NATIONAL ACADEMIES Advisors to the Nation on Science, Engineering, and Medicine pledge to Glaxo-Smith-Kline and Pfizer that if they developed and manufactured a safe, effective vaccine the government would buy X million doses at \$7 per dose. He continued by explaining that the private sector would be unlikely to invest in areas that have specific government requirements, such as the development of a next-generation submarine.

Finally, Kalil discussed the fact that some areas of innovation face a chicken-and-egg problem. For example, developing a new mode of transport such as electric vehicles requires the development and installation of charging stations. It would be helpful to have a taxonomy of areas such as these, where private-sector investment is difficult, Kalil reiterated. Such an effort could help with assessment, naming the problem, and developing appropriate metrics.

He also described other areas of intersection between financing innovation and other policy tools. For example, an NSF program called I-Corps delivers a curriculum to help scientists, engineers, and postdocs identify the "investment readiness" level of a new technology or service—for example, determining whether there is a business model for the idea under development, including partners, pricing, and market distribution channels. Faculty and teams who have gone through this curriculum are performing better by metrics of commercialization than those who have not.

The administration is also experimenting with "pull" approaches to innovation, which—unlike traditional "pull" approaches such as grants—identify an outcome of interest and pay for the outcome rather than inputs, said Kalil. As part of this effort, the administration worked with Congress to reauthorize the America Competes Act in a way that gives all agencies authority to support incentive prizes of up to \$50 million. Agencies have used this and other authorities to support over 300 incentive prizes posted on challenge.gov.

NASA and other agencies have also used milestone payments—paying a firm a certain amount of money (agreed upon in advance) for each milestone they achieve—which are good for supporting small companies that might not be able to do big upfront investment. And in the area of social policy, the idea of "paying for success" is emerging at the federal and state levels; for example, a nonprofit that is responsible for delivering an intervention to reduce recidivism would receive more money if its intervention is successful. The administration has also been working with Congress to make it easier for small firms to raise capital, said Kalil.

We need a concerted effort to recruit people who are public-minded enough to tackle important national problems, and finding novel sources of innovation financing could be one of them, said Kalil in closing. We also need to do a better job of training government people to use these tools, laws, and flexible authorities. he added.

Panel 1. Creating an Innovation Financing Ecosystem

The first panel on Tuesday, February 25, explored the topic of "Creating an Innovation Financing Ecosystem." The panel's goal, said moderator **Kathleen Harger** of the Innovation Financing Roundtable, is to introduce a new systems approach to financing translational R&D, so that it that can move at the pace of science, not at the pace of paperwork. "We hope to catalyze support and action for more effective financing to advance research from the bench into the marketplace, thereby improving America's competitive posture," she said.

Col. Mark "Puck" Mykleby, U.S. Marine Corps (retired) and a senior fellow at the New America Foundation, opened the panel with a presentation on "Sustainability: A 21st Century America Grand Strategy." Noting Thomas Paine's saying that "the cause of America is the cause of all mankind," Mykleby raised the question: What is the cause of America today? As a nation, we are perceived as the instrument of the status quo, he said.

We need to find a cause and a grand strategy, he continued. What would a grand strategy look like? Mykleby said that the nation's grand strategy going forward should be one of sustainability.

Defined as an organism's ability to remain diverse and productive over time, sustainability maps directly to our nation's enduring interests, he said. Sustainability means resilience, and we need to start discussing the integrated systems—food, transportation, education, our resilience and thereby our security—so that we can continue to compete and contribute in a global ecology.

Given Americans' use of resources, a quantitative measure of productivity or growth doesn't work anymore, Mykleby said. If everyone on the globe consumed Americans' amount of resources, it would require four and a half planets to sustain. He pointed to three major areas of large-scale demand that provide America an opportunities-based path to prosperity and security if we view sustainability as a 21st Century national strategic imperative: walkable

communities, regenerative agriculture, and resource productivity.

We need to use a systems approach and a framework to make improvements in such areas, he continued. The New America Foundation's Smart Strategy Initiative is in the process of creating an Economic Strategy Working Group, made up of private sector and academic institutions, to figure out the major policies that are needed. The group has created four regional clusters to take the concept of full-spectrum sustainability and create something that is investable and will have real value on Main Street, said Mykleby. If the real value that can be created from sustainability-in terms of jobs, public health benefits, etc.-can be captured and monetized and securitized and invested in, we will have the makings of an economic renaissance for the U.S., with sustainability at its core.

The next presentation was offered by Leslie Platt, president of the Innovation Financing Roundtable. The U.S. is at a transition point, and we can make a better future for ourselves and for the world, he said. Currently we have a 160-year old legacy funding system for R&D based on the Army's procurement processes. R&D is horizontal—it goes from basic research to proof of concept to the market—in defined scientific stages, tied to recognized milestones and investment expectations, but our federal R&D funding is vertical, unaligned and disconnected. Heavy administrative burdens, cumbersome federal cost accounting requirements, and payment on a reimbursement basis rather than as needed to support scientific work all add to the problems. Moreover, after each round of funding ends, there is a funding continuity gap, and those in research and development have to compete all over again for the next piece of funding.

The result of the contrast between the horizontal R&D path and the vertical, disconnected funding is that the capital markets cannot readily co-invest in federally supported innovation, said Platt. The goal



of the Innovation Financing Roundtable, which includes Lockheed Martin and other companies, Wall Street investment institutions, and senior public, private, academic and NGO representatives and stakeholders is to develop and support a better model, *i.e.*, a modern innovation financing ecosystem that aligns the capital markets, R&D performers, and federal and private funders.

Today, the entire federal government can move, under existing laws and authorities, to a commercial model that uses the tools of modern commerce, said Platt. By taking money from any source—federal, private sector co-investment, NGO—and putting it into standard commercial agreements, it is possible to achieve extensive private co-investment, funding continuity links, milestone payments, and advance market commitments. These actions can accelerate and expand R&D on promising innovative products conducted at the pace of science rather than paperwork, save much time and money, and create good jobs and economic growth.

By effectively using structured finance—for example, by creating a "capital stack" in which federal R&D funding can be used in tandem with private co-investment—we can provide major infusions of capital in an efficient, cost-effective horizontal financing path, making it possible for a successful R&D project to move through the process without funding gaps or excessive administrative burdens, said Platt. Other innovation financing constructs and tools are innovation bonds, hybrid and facility research bonds, and venture-bymilestone investments. Venture capitalists and other investors are ready to invest in promising R&D when there are well-designed and clearly defined projects, stages and ROI, net present value, and investment exit terms and expectations.

The Innovation Financing Roundtable is developing the framework for an innovation financing ecosystem and is putting together a cohort of translational projects to demonstrate that it can work. The group is contemplating holding the country's first Innovation Barn Raising and a Summit on Wall Street later this year. "As we move forward, the capital markets will line up to participate," said Platt.

The panel's final presentation was given by **Scott Fouse** of Lockheed Martin's Advanced Technology Laboratories. Fouse runs a small lab at Lockheed Martin that is 75 percent externally funded. The lab's role within Lockheed is to partner with the business areas and link them to the external funders such as DARPA, IARPA, and service labs. To do this, the lab also partners with small companies and universities.

The lab—which aims to be one of the innovation arms of Lockheed, with the goal of "creating and preventing technology surprise"—is organized around five technology areas: intelligent robotics, informatics, applied science, spectrum systems, and advanced concepts.

We want to be a "do" tank, and we are frustrated by the federal process, said Fouse. Why do we need the system Leslie Platt described? Because we're in a new reality where we don't have budgets or deep pockets anymore, he said. There is an opportunity in the proposed new system, because it allows partnering with commercial companies up front.

Suppose Lockheed is developing a new SR-71 aircraft using advanced technologies; rather than just building it for the military, the lab can think about all of the potential applications of those technologies up front. Such a system would also allow the lab access to IP that is outside of the aerospace industry. The idea of open standards is key, Fouse noted, because those standards would allow us to align government mechanisms with commercial ones.

Panel 2. Financial Innovations for Translational Biomedical Research

The next panel explored "Financial Innovations for Translational Biomedical Research." The first presenter was **Richard Basile**, founder of the BioPontis Alliance Rare Disease Foundation, who discussed the concept of the innovation joint venture. This is a general model for the advancement of early-stage biological discoveries that could become the basis for new drug and diagnostic candidates. To apply their model, the BioPontis Alliance has also launched a foundation focused on rare diseases in children.

BioPontis Alliance was established in 2009 as a consultancy by a multidisciplinary team of industry scientists and businesspeople, academics, investors,

contract research executives, and legal and accounting experts. The Alliance sought to address the innovation gap (also called the "valley of death") between academic basic discovery research and the industry's commercialization pipeline (Figure 1).

The early-stage research ecosystem has seen steady erosion in recent years, explained Basile, as traditional venture capital has slipped away, stakeholders have grown apart, and biopharmaceutical companies facing poor R&D productivity and globalization pressures abandoned basic disease research to focus resources on laterstage technology. The BioPontis Alliance identified the need for dramatic but pragmatic structural change to bring new solutions to the innovation gap. The model it developed to drive this change, the innovation joint venture, is not a pre-competitive collaboration. Rather, it is a formal economic and scientific joint venture and business partnership that integrates and aligns the interests of critical stakeholders by creating a new investment joint venture of both financial and knowledge capital.

Such a structure would need several critical design features, including the creation of a fully integrated partnership; investment management based on a diverse asset portfolio; the minimization of fixed costs through novel development partnerships with world-class contractors; collaboration that is transparent and provides appropriate IP and confidentiality protections for all partners; incentives to perform and a competitive rate of return for all partners; and clear contractual agreements regarding IP licensing, governance, and each stakeholder's contribution and rights to shared benefits.

Can all of this be achieved? Yes, said Basile. BioPontis Alliance set out to establish this joint venture, establishing partnerships with top-tier research academic institutions, top-tier contract research organizations, and biopharmaceutical companies seeking new candidates for product

Academic Research		Valley of Death		Industry	
Discovery Science	Lead Discovery	Lead Optimization	Pre-clinical studies (to IND)	Clinical Development	Product Registration & Launch

FIGURE 1 The "Valley of Death"

SOURCE: Presentation by Richard Basile, BioPontis Alliance Rare Disease Foundation, February 25, 2014

portfolios. BioPontis has executed formal agreements that establish incentives to de-risk the overall assemblage, development, and exit of a diverse technology portfolio with shared-value returns. "We've been working hard to diagnose the gap in the biopharmaceutical industry and bring a pragmatic structured platform to fill it," said Basile.

Andrew W. Lo of the MIT Sloan School of Management offered the next presentation, describing a new model—the megafund—that could de-risk the development of therapies for disease. Lo set the stage for his presentation by asking attendees to consider an investment opportunity that would require a \$200 million investment with a 5 percent chance of earning any return 10 years from now. "Who would be willing to invest their parents' savings or their childrens' college tuition money in this?" he asked. There were no takers in the audience.

This example is the back-of-the-envelope cost and probability of success for developing a single cancer compound. With a success, the present value of all future profits in year 10 would be \$12.3 billion, assuming the therapy generates annual net income of \$2 billion over the remaining 10 years of patent life. But there is a 95 percent chance of earning zero return. "For most investors, this is way too risky," said Lo.

Herein lies the conundrum, according to Lo: "Over the last decade, we've gotten much smarter at developing therapeutics—there are diseases that were death sentences a decade ago that have now become chronic manageable conditions—but during this same period the financial rates of return on biotech and pharma companies have been mediocre. Not surprisingly, venture capitalists and investment capital are leaving this space to pursue lower-hanging fruit in other industries. It's apparently much easier and less risky to develop an app and sell it to Facebook for \$15 billion than to develop an effective cancer treatment."

To address this challenge, Lo and his colleagues propose a new business model that uses the power of financial markets to fund these kinds of processes—a vehicle they call "the megafund." Instead of investing in one program at a time, we invest in 150 programs simultaneously, which would require up to \$30 billion in capital. The diversification changes the economics of the business because now there are 150 shots on goal and there is a 99.59 percent probability of having at least two successes among 150 independent trials. Given the reduction in risk, it would be possible to raise more than half the \$30 billion by issuing bonds.

After conducting a more realistic simulation using historical data from the Tufts Center for the Study of Drug Development, they found that it is possible to get decent rates of return by investing in a large number of risky projects: 5 to 8 percent on the debt side and 9 to 11 percent on the equity side. While these returns may not get venture capitalists excited, they are attractive to pension funds, sovereign wealth funds, and other large institutional investors. The closest existing model is a drug royalty investment company, the largest of which is Royalty Pharma, but these funds don't yet invest in early-stage assets. A new business model is needed.

Do we really need \$30 billion? According to Lo, the answer is yes for cancer drugs, but for other drugs it may not be necessary. His team recently ran a simulation for an orphan-diseases megafund and found that instead of 150 possible therapies for evaluation and \$30 billion, only 10 to 20 research programs and \$500 million are needed to generate rates of return of about 34 percent. On the other hand, \$30 billion would not be enough for addressing Alzheimer's disease because the costs of drug development are higher in this case, the success rates have been lower historically, and the basic science is not as developed—in fact, there aren't enough "shots on goal." Right now there are only a few promising hypotheses—beta amyloid and tau among them. As such, there is currently no way to de-risk an Alzheimer's portfolio. "The reason we have so many compounds and targets for cancer is that we made an investment in basic research over 40 years ago, when President Nixon declared a 'war on cancer' in 1971. We need to ramp up the basic science on Alzheimer's before we can make a dent," said Lo.

Dr. Lo acknowledged that there are many potential challenges to implementing the megafund model, but he expressed confidence that they can be dealt with by having financial economists collaborate with biomedical researchers, pharmaceutical executives, and venture capitalists. "We shouldn't declare war on disease, because it's the wrong metaphor," he said. "Instead, we should put a price on its head; greed is more sustainable than fear and anger." Apparently, we can do well by doing good. Lo concluded with the observation that "finance does not have to be a zero-sum game."

Presentations on Other Models: In-Q-Tel, Private Funding for Space Exploration, Science Foundation Arizona, Breakout Labs

The next presentation was given by **Jeffrey Smith**, a partner in Arnold & Porter, LLC, who explained the

founding and mission of In-Q-Tel, Strategic Investors for the CIA. In the late 1990s, it became clear that the CIA was not keeping up with technologies and that the drivers of new technology were venture capitalists and others in Silicon Valley. In 1999, the Central Intelligence Agency (CIA) established In-Q-Tel, an independent, nonprofit corporation whose mission was to identify commercial technologies with applications for the intelligence community.

The company has a 5-year charter agreement with the CIA and an annual contract, and it is overseen carefully by Congress. While In-Q-Tel is a strategic investor, it is not a venture capital firm, noted Smith. In-Q-Tel works with private investors to identify technology in its infancy that will have both commercial and government applications. The government benefits because it gets speed, innovation, and access to technology. Entrepreneurs. meanwhile, get revenue and customer feedback. Venture capitalists and other investors get access to intelligence community markets and other government markets, along with leveraged investment. For every \$1 of In-Q-Tel investment, Smith said, the company is able to leverage \$11 of venture capital money. In-Q-Tel's process is to 1) conduct a strategic needs assessment, leveraging insights from private capital; 2) develop a strategy; 3) conduct market surveys; 4) make strategic investments; and 5) oversee solution transfer.

To date, In-Q-Tel has evaluated 13,500 business plans, engaged with 4,700 tech companies, and invested in 225 companies, some from universities. Of these, 75 percent have resulted in pilot programs in the intelligence community. The technologies developed range widely, from cybersecurity and standoff threat detection, to language translation and social media analytics. For example, they identified a small company called KeyHole that was working with maps and they invested in it; Google spotted it, bought it, and used it as the foundation for Google Earth.

Presenting next was **Michael Potter**, senior fellow at the International Institute of Space Commerce, who spoke about financing for space science and exploration, as well as current challenges the field is facing. In the space world, he said, we talk about "no bucks, no Buck Rogers." Among the reasons for that shortfall is that politics always wins; people who have an engineering or technical background may come up with totally fantastic solutions to a problem but that may be totally irrelevant, said Potter.

"Why is humanity not on the moon?" ask Potter.
"And why does the U.S. today not have a man-rated

rocket?" There is no way to get U.S. astronauts into space today other than paying Russia to function as a taxi driver. "What is it about the structure of this system that has created these problems?" As current funding for the space sciences is under pressure, he said, there is "a growing realization that low budget, high-impact projects are the way to go."

The funding model frequently used by NASA and DOD is the cost-plus contract, and these are often painfully inefficient, said Potter. A new mode that is starting to get traction is the fixed-price contract, which can be structured to allow incremental payments based on success milestones. Private finance initiatives are another approach. In the traditional funding model, the Treasury Department gives funds to NASA, who then goes out and arranges contracts. Under a private finance initiative, funds from Treasury would be replaced by private finance, and the data from projects would be purchased by the government. In general, the current budgetary environment has made the government more open to collaborations with the private sector, he noted.

The private finance initiative was pioneered by the UK with the Skynet satellite, said Potter. Acting as the customer, the government contracted with the EADS group, who built the satellite and created a special purpose company, Paradigm. While the government didn't bend the metal or build the satellite, it agreed in advance to purchase the data from the satellite, guaranteeing Paradigm a revenue stream. This revenue stream was then used to approach the financial community to obtain private financing. This is an outstanding model that we should start looking at in the U.S., said Potter. One benefit is that it puts tremendous discipline on scientists to ensure that the data and instruments are really needed and meaningful. In the U.S. there may need to be legal changes to permit multi-year guaranteed governmental funding of revenue streams for space science projects.

The next presentation was delivered by **William Harris**, president and CEO of Science Foundation Arizona. Harris began by describing the Vision for Ireland, a technology foresight effort that began in 1999, and which he led beginning in 2001. The Vision for Ireland was a strategic plan for Ireland's growth as a knowledge-based economy. Its purpose was to move Ireland "up the value chain," moving from low-end manufacturing to a research and innovation-driven economy.

Ireland's deputy prime minister recruited Harris because they wanted someone outside who was not

involved in their competitive university system and would be trusted by all. The government had made a commitment of \$646 million Euros—nearly a billion dollars—and that funding would remain even if the current ruling party lost power. They wanted the initiative to be strategic and performance-focused.

"In Ireland, we gave longer, five-year grants to faculty so that they wouldn't have to spend so much time writing grant proposals, and we put in place incentives for them to work with industry," said Harris. From 2001 to 2006, they put in place external reviews of university research, and by 2003 to 2004 universities had been transformed rather significantly; they are still doing remarkably well. Industry was suspicious at first and thought the effort was a waste of government money. By the time Harris left, however, Intel and others insisted that the government continue its efforts and keep its established low corporate tax policy.

The program has improved Ireland's internationally recognized research capabilities, said Harris. In the 1990s Ireland was below the Organisation for Economic Co-operation and Development (OECD) average. By 2003 it was in 36th place, and by 2012 it was in 20th place overall—3rd in immunology research, 6th in nanotechnology research, and 8th in materials science. Even now Ireland invests about 150 million Euros per year; even during tough times they kept their commitment to science. That's a model we can think about for our states, said Harris, and one of the lessons learned from the project: that it is necessary to have a long-term commitment and consistency. There was a shared political consensus across the parties on the importance of quality education and the importance of having competitive talent driven by research for pragmatic reasons.

Dr. Harris was then recruited to try to replicate Ireland's success in Arizona. The initiative began with an investment of \$125 million over 5 years—far lower than Ireland had invested—but the effort wanted to see if we could catalyze the initiative in a U.S. state. The private sector matched every dollar the state put up. The core funds were paid for by CEO groups in the state. Their board was half instate, half out-of-state, and included a mix of people with experience in industry, academia, and start-ups. The goal was to create a competitive advantage for Arizona and a strategic advantage for the state's companies by partnering them with universities.

The initiative has given out 125 strategic research grants and has led to the start-up of 24 companies, as well as 207 patents and 23 cumulative technology licenses. The initiative also funds a

group of Bisgrove Postdoctoral Scholars—an exciting program sponsored by Science Foundation Arizona designed to attract and retain individuals who have demonstrated achievement and can transform ideas into great value—and a larger group of graduate research fellows who spend about 8 hours a week in K-12 schools helping teachers. This model is replicable and it's something other states can use, said Harris.

Importantly, Harris' experience in Ireland and Arizona makes clear that consistent public funding for research in strategic areas—for a period of 10 years—is essential to give industry and the university partners confidence in the system and to ensure that policy remains the same regardless of changes in the political leadership.

Lindy Fishburne, executive director of the Thiel Foundation's Breakout Labs, gave the final presentation of the day. The program that she directs was created out of concern over stagnation in innovation. Our country has amazing scientists with great ideas who can't get those ideas out of the lab and into the marketplace, said Fishburne.

Breakout Labs is trying to liberate the big, society-changing ideas and companies from the laboratory and bring them into the economy. "We have set up a revolving fund of philanthropic dollars, and we put that money into early-stage radical science companies across all advanced technologies," she said. "We give grants of up to \$350,000, generally to one or two people in a lab, and the goal is for them to use the money over a year or so to advance against very specific milestones. If they hit those milestones, they are in a much more attractive place to seek the followon funding they will need next." The Breakout Labs has also developed relationships with the follow-on funders, so that there are people to help carry the development forward.

The Breakout Labs is focused on spurring the development of radical big ideas, not just the next incremental piece of research needed to get the next grant, said Fishburne. Some of these ideas won't work technologically, but some will, and those that do should have a big impact.

The labs' sweet spot has been the intersection between biology and technology. Highlights of their recent work include biofabrication of meat and leather and modifying DNA in cells to create customized therapeutics.

The Breakout Labs uses a rolling Internet-based proposal submission process, followed by expert scientific review. The mandate is that there must be a significant scientific breakthrough at the core of the proposal.

The Breakout Labs is structured as a revolving fund, explained Fishburne. They provide a grant, but if the company is successful, the grant converts to equity and the Labs receive a small royalty. The hope is that the winners help build a stable fund and the program won't have to rely on philanthropic dollars year after year. "The revolving piece is starting, but we have a long way to go," said Fishburne.

Planning Committee for Novel Financing for Innovation: Stephen Cross (Chair), Georgia Institute of Technology; William Bonvillian, Massachusetts Institute of Technology; and Ellen Stofan, National Aeronautics and Space Administration.

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The summary was reviewed in draft form by Ralph Kuncl, University of Redlands and David Luzzi, Northeastern University, to ensure that it meets institutional standards for quality and objectivity. The review comments and draft manuscript remain confidential to protect the integrity of the process.

About the Government-University-Industry Research Roundtable (GUIRR)

GUIRR's formal mission is to convene senior-most representatives from government, universities, and industry to define and explore critical issues related to the national and global science and technology agenda that are of shared interest; to frame the next critical question stemming from current debate and analysis; and to incubate activities of on-going value to the stakeholders. The forum is designed to facilitate candid dialogue among participants, foster self-implementing activities, and, where appropriate, carry awareness of consequences to the wider public.

