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INNOVATION IN AMERICA: OPPORTUNITIES AND OBSTACLES

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BEFORE THE

SUBCOMMITTEE ON COMPETITIVENESS, INNOVATION, AND EXPORT PROMOTION

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION
UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

JUNE 22, 2010

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WITNESSES

INNOVATION IN AMERICA: OPPORTUNITIES AND OBSTACLES

TUESDAY, JUNE 22, 2010

U.S. SENATE,
SUBCOMMITTEE ON COMPETITIVENESS, INNOVATION, AND EXPORT PROMOTION,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:34 p.m. in room SR–253, Russell Senate Office Building, Hon. Amy Klobuchar, Chairman of the Subcommittee, presiding.

OPENING STATEMENT OF HON. AMY KLOBUCHAR, U.S. SENATOR FROM MINNESOTA

Senator KLOBUCHAR. Good afternoon, everyone. Thank you so much for coming today. We're going to be talking today about a very key subject to our economy, to our economic recovery, and really to America's standing in the world, and that is innovation.

I'd like to thank everyone that's here, especially The Honorable Aneesh Chopra, who is the Chief Technology Officer and Associate Director for Technology, Office in Science, Technology Policy. The President has named as his point person on these technology innovation issues. He is on our first panel.

And then, after that, we have a second panel, and I will introduce the witnesses when they come up.

But, I'd first like to thank Andy Weiss, who is the CEO of CoAxia. CoAxia is a small medical device company based in Maple Grove, Minnesota. And I think it's very important here that we could have had CEOs from big companies, but a lot of our entrepreneurship and innovation starts in America with our smaller companies. I know, personally, Medtronic started in a garage; 3M, in Minnesota, started as a sandpaper company in Two Harbors, Minnesota; and Target started in a dry goods store. That has been the story of America. It's a story of innovation.

The world has always looked to our country as a center of innovation and entrepreneurship, a place where even the smallest startup from the humblest beginnings can grow into a household name.

My state, the State of Minnesota, is a state that brought the world everything from the pacemaker to the Post-it Note; and despite being 21st in the country for population, we are now 7th for Fortune 500 companies. And, as I said, these all started as small businesses.

I'm certain that the next Medtronic, 3M, or Mayo Clinic is being created right now in a lab or in a garage or in a manufacturing plant, and it is our job to support these innovators and entrepreneurs, and to allow them to bring these products to the market. The road from concept to commercialization is full of hurdles to jump and barriers to overcome, and we should focus our efforts to smoothing this road.

I'm pleased to be here with my colleague, Senator LeMieux, the Ranking Member on this committee, from the State of Florida. And we have worked together on an export promotion bill to help small and medium-sized businesses. It actually got marked up through this committee 2 weeks ago.

We know that, every day in every State, small companies are dreaming, doing, and driving the innovation agenda that we need to compete in this world economy. Whenever I think about this issue, I think about the beginning opening ceremony in the Beijing Summer Olympics, with the 2,000 perfectly synchronized drummers. Well, those drumbeats are only getting louder and louder. And while China is investing billions in its technology sector, we're still trying to get figure out some regulations. And while India encourages invention and entrepreneurship, we are still, sadly, playing "Red Light, Green Light" with stop-and-go tax incentives. And while Brazil is training more engineers every day, we are doing our best, but we simply still haven't reached that point of graduating engineers and scientists to the degree to compete in this world economy.

The world is moving ahead fast, and we can't let it pass us by. We need to be a country that exports, that thinks, and that invents, and that makes stuff again. In the words of Minnesota native and *New York Times* columnist Tom Friedman, "We need to do some nation-building in our own Nation."

So, how do we do this? How do we encourage innovation? Well, first and foremost, we need policies that galvanize investors and encourage companies to grow. And that includes a strong and consistent R&D tax credit. We need greater investment in small business innovators through programs like the Small Business Innovation Research Program and the Small Business Technology Transfer Program. I saw Senator Warner just walked in; I know he has been working very hard—a group of us have been working hard on making sure that credit is getting out there to small businesses, as well.

We need an education system that emphasizes STEM courses, like math and science and engineering, a system that trains our children for jobs in a 21st-century economy, to do the kind of innovative work that needs to be done.

We need to allow people that study in this country from other countries, that come and work in our universities, that have graduate degrees, to stay in this country and start the next Google.

America has many innovative industries and companies, high-tech companies—IBM, Symantec—we've mentioned a number of them today—and we're going to hear from the biotech/high-tech industries today.

But, I did want to focus on one issue which is very important in my State. And I know we're going to hear from some of the medical

device industry people. I want you think about medical device in another way, besides saving my hip, and that is that the medical device industry is a poster child for American innovation. The U.S. is the world's number-one exporter of medical devices, and the medical device industry is one of the few industries that, even today, is adding jobs. From 2000 to 2007, from 2007 to 2008, employment in the overall economy went down by 0.7 percent, but jobs in the medical device industry increased by 1.5 percent. The industry is expanding for a number of reasons. One reason is that the science behind these devices is improving, and every day doctors and scientists come up with new materials, new ways of diagnosing diseases, and new ways of treating medical conditions.

The industry is also expanding because advanced medical care is expanding throughout the world. Just think about the growing customer base in China and India. The middle class in these countries is increasing at an amazing rate. And with this expansion, the industry should also continue to grow.

Not only is the medical device industry creating jobs in America, it is creating good high-paying jobs. Medical device jobs pay around 30 percent more than the average American job.

Minnesota, in my State, has led medical innovation for more than 60 years and boasts more than 400 medical device companies that, together, employ more than 50,000 people. Plus, for each job created by the medical device industry, 4.5 additional jobs are created in the overall economy.

So, this is truly an industry that we can look to as we look to how we expand this economy. When 95 percent of our potential customers, for any American business, are outside of the borders of the country, you should look to medical device.

I did want to mention one roadblock that we're going to be discussing, and that is what's happening right now with changes to the FDA's 510(k) approval process. This is an expedited process by which the FDA approves medical devices when a substantial equivalent of that device is already on the market. Currently, 90 percent of devices on the market were approved using the 510(k) process.

Changes to this process are always welcome. Safety should be the number-one focus. But, what's happening right now is that these changes are happening in the middle of individual companies' approval processes. For example, the FDA is asking for clinical data for devices that never before required clinical data, with no warning to device companies that such data would be needed. The device companies could not have predicted that the FDA was going to need this data, because these types of devices have not had any problems in the past. These requests obviously delay the approval process. And the longer the approval process, the longer it takes to get a lifesaving technology to market. The longer it takes to get a new device to market, the less certainty investors have and the more capital businesses need.

Already, FDA's inconsistent approval process has dampened investment. In the last 2 years, venture capital funding alone has dropped by one-third. These declines have forced many small manufacturers to close their doors. Still others have picked up and relocated to Europe, taking jobs and revenue along with them.

I'm aware of one American company that has had tremendous trouble with this process. The company and the FDA reached formal agreements regarding what kind of studies the company needed. The company completed those studies, with great results. However, the FDA, on multiple occasions, still goes back and asks for additional studies. The FDA kept changing the rules, even though the product had been approved in the market in Europe for 10 years. That's 10 years. The company is now going out of business. At its height, it had around 50 employees.

So, that's why I think it is very important, even for the best intentions, that we make sure that we mesh what's going on at our regulatory agencies with what we're doing to encourage innovation.

I still believe that the industries we're going to hear from today—high tech and biotech, as well as medical device—are really key to our economic fortunes in the country, and others should be brought along, as well, that can really create these jobs, can export to the world, create a world of opportunity, and bring our economy back to where it once was.

So, I'm excited to hear from our witnesses today—and I want to thank you for coming.

And I'll turn it over to my colleague Senator LeMieux.

STATEMENT OF HON. GEORGE LEMIEUX,
U.S. SENATOR FROM FLORIDA

Senator LEMIEUX. Thank you, Madam Chair. I want to thank you, Senator Klobuchar, for calling this hearing, and continuing this discussion on the need to improve innovation and competitiveness. It follows, as you mentioned, on the hearings that we had on exports, specifically focusing on how we can help spur development and improvement in small and mid-sized businesses.

Advancements in science and technology and methods of providing products and services are the foundation of economic prosperity, and advance our security interests, as well. But, as the Information Technology and Innovation Foundation documented in a recent report, the Atlantic Century, the United States has slipped from number one in global innovation-based competitiveness to number six. The report identifies several reasons for this, including declines in domestic research and development delays for new U.S. patents, and a downturn in the number of candidates seeking science and engineering degrees.

We have a responsibility in the Congress to work toward ensuring Americans have every opportunity to compete in the world marketplace. Congress has been focused, but a more laser-like focus is required for the encouragement of candidates seeking math, science, and engineering degrees.

We need modern and enforceable immigration policies that afford an opportunity for us to retain the best and brightest minds who come here seeking higher learning. We also need the kind of flexibility in our regulatory framework that recognizes that government should foster, rather than stifle, the entrepreneurial spirit.

The recession has put enormous pressure on small and mid-sized businesses, as well as investors, to find new and more economic ways to remain competitive.

I look forward to our hearing today, and hearing from our witnesses about measures that would help advance our innovation and competitiveness in the world.

I would like to specially recognize my friend, Mr. Rhys Williams, who is the President of New World Angels. He is a successful entrepreneur, and New World Angels is the largest angel investor group in Florida. He brings a unique perspective on the need of small firms and the bridging of what we call the Valley of Death, the—between innovation and the marketplace—I know Senator Warner and I have talked about that before—which is really a focus. You have this great support in our universities, especially for scientists and entrepreneurs and innovators who can develop things there in the lab. But, getting that funding in that middle area before it's marketable is very challenging, and it causes a lot of stifling of innovation.

Madam Chair, this is a hearing that is very important to Florida. Florida is trying to diversify its economy. We are now under tremendous pressure, in this recession, with nearly 12 percent unemployment, one of the Nation's worst foreclosure rates, one of the worst rates in folks being behind on their mortgages. And that is because we've been too reliant upon real estate and construction, and a couple of other industries, to make our economic engine run.

Recently, in past years, we have attracted the life sciences business and other high-tech businesses to Florida, whether it's Scripps, whether it's Max Planck, whether it's the Medical Village in Orlando, or the great work that our universities are doing. This is a key focus for Florida, to help us diversify and advance our economy.

So, I thank you very much and congratulate you on calling this hearing today.

Senator KLOBUCHAR. I'll now hand it over to Senator Warner, who knows a little bit about this, as he started his own business. I'm remembering, I know you two know each other well, when we had a hearing on cell phones, and there were three Senators up here chairing it. Senator Warner was brand new, had to go down to his seat down there, and I actually sent a note to him, as everyone was droning on, that said, "What the hell do you think you know about this?"

[Laughter.]

Senator KLOBUCHAR. So, I'm glad he has taken his rightful place, as he should, as a leader on these issues.

Senator Warner.

STATEMENT OF HON. MARK WARNER, U.S. SENATOR FROM VIRGINIA

Senator WARNER. Thank you, Madam Chair. Thank you, Senator Klobuchar. And I guess I'm moving up the dais a little bit.

Let me echo Senator LeMieux's comments and thank you for holding this hearing. It is long overdue. And I appreciate your interest in both competitiveness and innovation. I also particularly appreciate your focus on exports.

As Senator Klobuchar has said, the markets of tomorrow are not just going to be domestic, they're going to be all over the world. And I really appreciate you bringing this hearing, and particularly

having our chief technology officer for the country, a great Virginian, Aneesh Chopra, who I've had the pleasure of knowing for more than a decade. And I don't want to steal his thunder. Aneesh will give us a good presentation on what the administration is doing, and I look forward to asking him a couple of questions.

I do want to make a couple of opening comments. I mean, and this is not very PC, but I don't think our country's had much of an innovation or growth strategy for the last decade-plus. And I think, if you look at most metrics, compared to late 1980s and through most of the 1990s, innovation in America has been, at best, lackluster. I'm not trying to point political blame. I think there was a little bit of resting on our laurels as the rest of the world leaped ahead. And there are clear exceptions, companies in the last decade that have been extraordinary successes, but they pale in comparison to the numbers that took place during the 1990s.

And I think there are three or four areas that, beyond this hearing, I'd love to work with my colleagues and others on. One is—and I think we'll get to this in a second panel—this is something I've been working with Dr. Atkinson on—America is one of the few major industrial countries in the world that doesn't even have a competitiveness strategy that's clearly outlined, that we can at least peg with metrics against how we're doing. If you look at some of the countries around the world—the Koreas of the world, who have grown enormously in innovation in the last decades-plus—they've got a strategy and a plan.

Second, I do think there needs to be—and both Senator LeMieux and Senator Klobuchar have mentioned this—we're going to need a system that looks a little better at the regulatory system. Too often, our regulatory system has become an impediment to innovation. Senator Klobuchar mentioned the FDA. I think we've seen challenges around the energy sector, well-intentioned environmental regulations sometimes precluding energy innovation. And this is tough, as a former telecom and IT guy, to say, but I think the greatest job and wealth creator in the next 25 years, worldwide, will be the energy sector, and, in many areas, we're not in the game. And while there are enormous challenges we've got to wrestle with, on IP protection that this committee's jurisdiction has got to take on the one area, regardless of where we fall on that issue is upgrading the caliber and length of stay of folks at the Patent and Trade Office, to make sure that those innovations can at least be reviewed in a timely manner. That is very important.

Exports has been mentioned as an area that needs more attention.

And then, my final comment—I know my time has run over—and I'm very happy that Senator LeMieux has got—one of the second panel—a guy who was an angel investor coming up—but, one of the areas that we've had the most precipitous decline in the last decade is the slowing of early-stage capital formation in this country. Let's face it, over the last decade, why would anybody—I'm biased; I used to be a venture capitalist, I used to be somebody who started these companies—but, why would anybody go out and do the very hard work of investing with an entrepreneur, growing that company through that Valley of Death, when, over the last decade,

a much surer bet was to go be a financial engineer on Wall Street and create a financial product that was supposed to be about lowering the price of risk, when, in reality, all we did was create an interconnected network of financial obligations that almost brought the country, and the world, to the brink of financial ruin?

Now, some of those instruments are useful. Many of them are more about fee generation, I think, than lowering the price of risk. And it would be great to have a few less financial engineers and a few more real engineers that actually build something. And one of the challenges is that we've got—and I say this as we look at the migration toward hedge funds, private equity—and, candidly, even in the venture capital community—everybody's moved up the food chain to do larger and larger deals, so the absence of angel funding, the absence of early-stage venture funding, has made it extraordinarily difficult for those startup companies, whether they come out of the university lab or whether they come out of the garage, to get past that angel round, and friends-and-family round, to get that funding, to where the venture community now looks at deal size. Oftentimes, you know, many of the venture community looks at a minimum $10-million investment. You're going to be through the Valley of Death if you can rate a $10-million investment, with very few exceptions.

So, I appreciate, again, the Chair bringing this hearing. I look forward to Aneesh's comments, and look forward to the questions.

Thank you.

Senator KLOBUCHAR. Well, very, very good. Thank you, Senator Warner.

Our first panelist, as I said, is Mr. Aneesh Chopra, who is the Chief Technology Officer and Associate Director for technology within the White House Office of Science and Technology Policy. He is our country's first-ever national Chief Technology Officer, a job he entered after serving as the Secretary of Technology for the Commonwealth of Virginia.

A entrepreneur himself, he is a Co-Founder of Avatar Capital, a venture capital network that invested in 18 startups during the dot-com boom. Mr. Chopra is a strong advocate for the medical device industry, and is also a self-proclaimed "tech geek" who likes technological devices. We like that, on this subcommittee. This is a welcome place for you.

Mr. Chopra, thank you for being here.

STATEMENT OF HON. ANEESH CHOPRA, CHIEF TECHNOLOGY OFFICER AND ASSOCIATE DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY POLICY, EXECUTIVE OFFICE OF THE PRESIDENT OF THE UNITED STATES

Mr. CHOPRA. Thank you so much.

Chairwoman Klobuchar, Ranking Member LeMieux, and, of course, my dear friend and Senator, Mark Warner, it's a real pleasure to be with you today to discuss the President's strategy for American innovation.

We do have more thoughtful and formal prepared remarks, which I'll leave for the record and just describe for you some of the key themes and case studies that I'd like to highlight.

I'd like to begin by referencing the themes that were raised in your opening remarks, and highlight specifically the study Senator LeMieux referenced about ranking from first to sixth. The more telling statement was, for the decade that Senator Warner had just mentioned, the rate of change that we'd seen across the 16 metrics that Dr. Atkinson will describe later. We ranked 40th out of 40 countries in the degree to which we saw improvement across this index of 16 measures.

So, yes, one to six is an important specific statistic, but that rate of change is the one that has us a little bit more concerned.

In my capacity as Chief Technology Officer, it is my responsibility to execute on the President's strategy for American innovation, by highlighting the power of data, technology, and innovation, both to improve the Nation's economy and to improve the lives of everyday Americans.

And with your permission, what I'd like to do briefly is summarize the key components of the President's strategy for our discussion today.

The strategy rests on the notion that our country's at its best when we invest in the building blocks of innovation. We'll talk about R&D investments, the human capital aspect, and STEM education, as well as the information technology infrastructure necessary, whether it be broadband or other related capabilities.

The second component of the strategy is that we look at open and competitive markets, with particular emphasis on entrepreneurship. I'm going to come back to this second pillar for my case studies.

And then, last but not least, the President has identified a few areas that he has called for an "all-hands-on-deck" approach to catalyze breakthroughs. We speak directly—and address, Senator Warner, your comments—about the opportunities in clean energy and in healthcare information technology, a conversation that we will have later today.

I'd like to highlight three examples, though, in this middle category, about focusing on entrepreneurship, and highlight for you examples on where our strategy is taking hold and where we're hoping to move forward.

First is on the issue of technology transfer. The Administration is committed to strengthening the capacity of economic regions to commercialize research through entrepreneurship. In May, the Commerce Department released the I6 Challenge, in collaboration with the National Institutes of Health and the National Science Foundation, offering up to $12 million in grant funding specifically to reward six teams around the country who have demonstrated the capacity to move ideas from the university setting to the marketplace. This particular program is active right now. Applications are due by July 15. It will focus on startups like a company called "iRhythm Technologies," which was born out of Stanford University's Office of Technology Licensing, back in 2006, with a powerful mission to both improve access to heart rhythm monitoring services, up to a full 14 days of monitoring, through a simple patch—and get this—that costs no more than today's more prevalent monitoring technologies that, frankly, dangle wires all over your body and often limit the monitoring time to a day, 2, or 3.

Earlier this month, iRhythm formed a strategic partnership with St. Jude Medical that included a $10- million early-stage capital investment to deliver these innovative products to market, and that now supports, what had been a single-person faculty member's startup in 2006, a company that has over 80 employees manufacturing domestically here in the United States and delivering those innovations throughout the country, and, as you all alluded to, the opportunities for export.

The second component of entrepreneurship I'd like to highlight is the President's commitment to an open and transparent government. On the President's first full day in office, he directed us to instill a new culture of open government. And as part of that commitment, Secretary Sebelius, in early June, specifically highlighted the Community Health Data Initiative specifically to spur entrepreneurial activity born off of information that we've held within our databases at the Department of Health and Human Services. We met an entrepreneur, living in rural Wisconsin, by the name of David Van Sickle, who hailed from a community that had struggled with the issue of asthma reporting. He developed a platform that would help patients and public health professionals track the geography of asthma attacks by attaching a real-time GPS sensor to the inhaler so that it would record not only the location, but the time when it was activated. This has allowed for a much broader health surveillance system that would allow communities and individuals to avoid specific environmental conditions and be more preventive in their orientation with respect to asthma-related concerns.

I will end my remarks, given the time here, to highlight the importance of innovation clusters and the work that we're doing, and I'll end with this simple statement: We do believe that the United States is still the land of the future. We retain this honor because of America's scientists and entrepreneurs, and the public and private sectors, who are all coordinated and organized to understand the importance of applying the power of American curiosity and ingenuity to the biggest economic and social challenges of our time.

With that, I'd look forward to your questions, comments, and concerns.

[The prepared statement of Mr. Chopra follows:]

PREPARED STATEMENT OF HON. ANEESH CHOPRA, CHIEF TECHNOLOGY OFFICER AND ASSOCIATE DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY POLICY, EXECUTIVE OFFICE OF THE PRESIDENT OF THE UNITED STATES

Chairman Klobuchar, Ranking Member LeMieux, and members of the Subcommittee, it is my distinct privilege to be here with you today to discuss the Obama Administration's Strategy for American Innovation.

President Obama understands the importance of innovation for sustainable growth and quality jobs. On September 21, 2009, he released his *Strategy for American Innovation* that identified three critical roles for the Federal Government: to invest in the building blocks of innovation; to create the right environment for private sector investment and competitive markets by, for example, promoting high-growth entrepreneurship, protecting U.S. intellectual property rights, and fostering an open government; and to serve as a catalyst for breakthroughs related to national priorities such as clean energy, health care, and other "grand challenges" of the 21st century.

In my capacity as Assistant to the President, Chief Technology Officer, and Associate Director for Technology in the Office of Science and Technology Policy, my mission is to harness the power and potential of technology, data, and innovation to

transform the Nation's economy and to improve the lives of everyday Americans. The Administration envisions an economy in which jobs are more plentiful, American firms are more competitive, Americans are safer and more secure, and energy use is cleaner and more economical.

Problems with the Bubble-Driven Growth of the Past

Despite the American economy's historic strength, our economic growth has rested for too long on an unstable foundation. Time and again, explosive growth in one sector of our economy provided a short-term boost while masking long-term weaknesses. In the 1990s, the technology sector climbed to unprecedented heights of valuation. The tech-heavy NASDAQ composite index rose over 650 percent between 1995 and 2000, but then lost two-thirds of its value in a single year.

After the tech bubble burst, a new one emerged in the housing and financial sectors. This type of growth isn't just problematic when the bubble bursts, it is not entirely healthy even while it lasts. Between 2000 and 2007 the typical working-age American household saw its annual income decline by nearly $2,000.

A short-term approach to the economy masks under-investments in essential drivers of sustainable, broadly-shared growth. It promotes temporary fixes over lasting solutions. This is patently clear when looking at how American education, infrastructure, healthcare, energy, and research—all pillars of lasting prosperity—were ignored during the last bubble.

Despite this underinvestment in key drivers of growth, the American economy remains the most dynamic, innovative, and resilient in the world. America's strengths are clear: world-class research universities, flexible labor markets, deep capital markets, and an energetic entrepreneurial culture. The United States must redouble its efforts to give our world-leading innovators every chance to succeed. America cannot rest on our laurels while other countries are catching up.

The Need for Innovation

Innovation is at the core of a new foundation for durable, sustainable expansion in both employment and economic growth. Robert Solow won the Nobel Prize in economics by showing that factors other than capital intensity, most notably advances in human knowledge and technology, accounted for almost 90 percent of the growth in America's output per hour in the first half of the last century. Growth accounting has been refined since Solow's first attempts, yet contemporary research still shows that human skill and innovation remain far and away the most powerful force for improving prosperity over the long-run, which is exactly what we need.

Given its importance, the process of innovation cannot be taken for granted. Innovation begins from scientific research that creates new opportunities for technological change. That basic research lays the groundwork for the *development* of new products, services, or processes. But it does not end there. To create value, a new idea must be implemented. Thus successful innovations will diffuse throughout an economy and across the world, impacting various sectors and sometimes even creating new ones. A diffused innovation must then scale appropriately, reaching an efficient size at which it can have a maximal effect.

The full process—from development to diffusion to scaling—has many variables and many inputs. Ideas often fail before they make it through the full chain. But those that do succeed can create value and jobs while improving people's lives.

For societies to prosper—both as producers of goods and services as well as consumers of them—innovations need to flourish and progress along this chain. And here, government has a fundamental role to play.

The Appropriate Role for Government

While it is clear that a new foundation for innovation and growth is needed, the appropriate framework for government involvement is still debated. For the Obama Administration, the arguments about too much or too little government involvement in innovation policy often lead to unproductive debates. The real question is how can government best create the conditions that will enable private sector entrepreneurs to innovate. Stated differently, the real issue is how to enable entrepreneurs to move our economy forward. As explained in the Innovation Strategy document, the best way forward is for the United States to invest in the building blocks that only the government can provide, protecting an open and competitive environment for businesses and individuals to experiment and grow, and by providing extra catalysts to jumpstart innovation in sectors of national importance.

A Strategy for American Innovation

President Obama has already taken historic steps to lay the foundation for the innovation economy of the future. In the Recovery Act alone, the President committed over $100 billion to support groundbreaking innovation with investments in

energy, basic research, education and training, advanced vehicle technology, health IT and health research, high-speed rail, smart grid, and information technology.

The Obama Innovation Strategy has three parts: investing in the building blocks of innovation, promoting competitive markets that spur productive entrepreneurship, and catalyzing breakthroughs for national priorities.

Investing in the Building Blocks of American Innovation

President Obama is committed to making investments that will foster long-term economic growth and productivity. These investments are in areas that include research and development, a skilled work force, a leading physical infrastructure, and widely available broadband networks.

Recognizing the need for long-term and sustained investments in R&D, President Obama has pledged to complete the doubling of funding for three key science agencies, the National Science Foundation, the laboratories of the National Institute of Standards and Technology, and the Department of Energy's (DOE) Office of Science. In his landmark address before the National Academy of Sciences, President Obama set a goal of lifting the sum of public and private investment in R&D to 3 percent of GDP, which would exceed the level achieved at the height of the space race. As the President noted, "science is more essential for our prosperity, our security, our health, our environment and our quality of life than it has ever been before."

To encourage private sector investment in R&D, the President has proposed making the Research and Experimentation Tax Credit permanent. The Obama Administration is working to increase the impact of this investment by providing greater support for university commercialization efforts, for high-risk, high-return research, for multidisciplinary research, and for scientists and engineers at the beginning of their careers. For example, the National Science Foundation's FY11 budget proposes to double support for the Partnerships for Innovation program, which will help universities move ideas from the lab to the marketplace.

The Obama Administration is committed to expanding access to broadband. This past April, the Federal Communications Commission (FCC) released the National Broadband Plan, called for in the American Recovery and Reinvestment Act, to identify ways to expand access to broadband and promote economic growth and job creation.

In his statement on the plan's release, the President committed to "build upon our efforts over the past year to make America's nationwide broadband infrastructure the world's most powerful platform for economic growth and prosperity." To that end, I've established a Broadband Subcommittee of the National Science and Technology Council's Committee on Technology, to focus closely on the plan that the FCC—an independent agency—produced, and to advise the Administration on the actions it should take to promote broadband as a platform to improve the lives of everyday Americans and drive innovation in the economy.

Promoting Competitive Markets That Spur Productive Entrepreneurship

The Obama Administration believes that it is imperative to create a national environment that is ripe for entrepreneurship and risk taking, and allows U.S. firms to compete and win in the global marketplace. The Administration is pursuing policies that will promote U.S. exports, support open capital markets, encourage high-growth entrepreneurship, invest in regional innovation clusters, and improve our patent system. The Administration also strongly supports public sector and social innovation.

Competitive, high-performing regional economies are the building blocks for national growth and job creation, and the Administration is stepping up its efforts to cultivate regional economic clusters across the country. For example, the Administration recently announced that seven Federal agencies would work together on a $130 million competition for an Energy Regional Innovation Cluster (E–RIC) around one of DOE's Energy Innovation Hubs. The Department of Commerce's Economic Development Administration is one of the partners, and will be contributing funds to link the Hub with local economic development strategies and to support economic adjustment efforts in the local community. This pilot project is designed to spur regional economic growth while developing energy efficient building technologies, designs, and systems. This will allow a region to develop a strategy that includes support for R&D, infrastructure, small and medium-sized enterprises, and workforce development. What we are learning is that whether the investment comes from the Federal or state government, or the private sector, or ideally, all of the above, those dollars will do a lot more good if they serve a well-developed regional strategy that leverages core regional strengths.

The i6 Challenge launched by the Commerce Department's Economic Development Administration, the National Institutes of Health, and the National Science

Foundation, is another example of these efforts. A total of $12 million is available to six teams around the country with the most innovative ideas to drive technology commercialization and entrepreneurship in their regions. The i6 Challenge is aimed at bringing together entrepreneurs, investors, universities, foundations and non-profits in communities throughout the United States, with applications due by July 15, 2010.

Innovation must occur within all levels of society, including the government and civil society. The Obama Administration is committed to increasing the ability of government to promote and harness innovation. The Administration is encouraging departments and agencies to experiment with new technologies that have the potential to increase efficiency and reduce expenditures, such as cloud computing. The Federal Government should take advantage of the expertise and insight of people both inside and outside the Federal Government; use high-risk, high-reward policy tools such as prizes and challenges to solve tough problems; support the broad adoption of community solutions that work; and form high-impact collaborations with researchers, the private sector, and civil society.

The Administration launched the White House Open Government Initiative to coordinate Open Government policy, support specific projects, and design technology platforms that foster transparency, participation and collaboration across the executive branch. The principles of open government help to advance a set of key national priorities with emphasis on demonstrating tangible benefits for the American people.

An example of how prizes are being used to spur national priorities is USDA's Apps for Healthy Kids challenge that was launched by First Lady Michelle Obama in March as part of her Let's Move initiative. The competition is based upon a recently released set of data on nutrition by USDA and is aimed at encouraging entrepreneurs, software developers and students to create applications and games that encourage children and parents to make more nutritious food choices and to be more physically active. Eight game jams, bringing together developers to share tips and ideas, have been held across the country, and over twenty applications have been submitted so far in advance of the contest deadline on June 30.

Catalyzing Breakthroughs for National Priorities

President Obama is committed to harnessing science, technology and innovation to unleash a clean energy revolution, improve America's health care system, and address the "grand challenges" of the 21st century.

Smart Grid Technologies

Modernization of the Nation's electric grid is a vital component of efforts to build a low-carbon economy. The "smart grid" will help provide consumers with the information, automation, and tools they need to control and optimize energy use. The tools and services enabled by the smart grid promise improve the reliability, security, and efficiency of the electric grid. Smart grid technologies can also facilitate energy generation from clean energy supplies and enable more effective integration with the electricity delivery system of renewable energy sources, demand response resources, and plug-in electric vehicles. The National Institute of Standards and Technology (NIST) has coordinated an unprecedented, open and transparent public/private collaboration involving over 550 companies, organizations and government agencies to create the interoperability standards needed to foster innovation in the electric grid.

Last March, in conjunction with NIST, we broadened participation by launching the Smart Grid Forum, an on-line forum focused on the Nation's energy consumers with an emphasis on spurring innovation in smart grid products and services. We received comments from over 130 individuals and organizations contributing their solutions to some of the most challenging smart grid goals that we have—from deployment of smart grid solutions, to development of standards needed for information exchange, to ensuring cybersecurity in the smart grid. Following the input received in that forum, I established another Subcommittee of the National Science and Technology Council's Committee on Technology to enable the Administration to develop a comprehensive policy framework for Smart Grid policy.

Healthcare IT

Another important Presidential priority is improving our health care system. Broad use of health information technology has the potential to improve health care quality, prevent medical errors, increase the efficiency of care provision and reduce unnecessary health care costs, reduce paperwork, increase administrative efficiencies, expand access to affordable care, and improve population health. The Recovery Act provides support for the deployment of health information technology, such as electronic health records. The Office of the National Coordinator for Health

IT and the Centers for Medicare & Medicaid Services are working to ensure that health information technology products and systems are secure, can maintain data confidentially, can work with other systems to share information, and can perform a set of well-defined functions. NIST, in coordination with the Office of the National Coordinator and others, is accelerating the adoption of health IT standards by providing the critical testing infrastructure needed to achieve these goals.

Last February, the Office of the National Coordinator for Health IT announced a new collaborative, *NHIN Direct*, which will organize a set of standards, services and policies that enable secure health information exchange over the Internet (*www.nhindirect.org*). Several Federal agencies and healthcare organizations are already using the Nationwide Health Information Network (NHIN) technology to exchange information amongst themselves and their partners. This new effort will provide an easy "on-ramp" for a wide set of providers and organizations looking to adopt the exchange of health information—and provide a framework to spur innovation in support of direct communication amongst providers, and between providers and patients—in a secure and simple manner.

The recently launched Community Health Data Initiative (CHDI) is another effort demonstrating how data and the innovative uses of technology are resulting in immediate improvements to health care. A public-private collaboration spearheaded by the Department of Health and Human Services, CHDI is aimed at using health care data to raise awareness and improve community health performance. Innovators from the worlds of business, technology, academia, and community organizations identified areas where exciting new applications to improve health could be developed. In less than 12 weeks these partners put together an amazing array of new or improved applications that utilize our data in creative and powerful ways to help advance health care. The results of these efforts, unveiled in early June, included the integration of patient satisfaction ratings from Medicare's Hospital Compare database into the web search results for hospitals, and a brilliant new combination of GPS device and app that allows asthmatics to have their inhalers automatically transmit the location and time of each use—producing an anonymized, real-time map of asthma incidence that can provide crucial guidance regarding how to target interventions to reduce the burden of asthma.

Existing technologies are also being used in innovative ways to improve health education, through the Text4Baby campaign that was launched in February. Text4Baby is a free mobile health education service to promote maternal and child health. Expecting mothers can text baby, or bebe in Spanish, to 511411, and they will receive free SMS text messages each week, timed to their due date or their baby's date of birth. Fifteen wireless carrier have agreed to deliver Text4Baby messages to subscribers at no charge for 2 years, and as a result, nearly 50,000 individuals have signed up for this services since February.

Grand Challenges

Finally, the Obama Administration believes that grand challenges should be an important organizing principle for science, technology and innovation policy. They can address key national priorities, catalyze innovations that foster economic growth and quality jobs, spur the formation of multidisciplinary teams of researcher and multi-sector collaborators, bring new expertise to bear on important problems, strengthen the "social contract" between science and society, and inspire students to pursue careers in science, technology, engineering, and mathematics. The President's innovation strategy sets forth a number of grand challenges, such as solar cells as cheap as paint, educational software that is as compelling as the best video game and effective as a personal tutor, and early detection of diseases from a saliva sample. The National Economic Council and the Office of Science and Technology Policy are encouraging multi-sector collaborations to achieve these grand challenges that might involve companies, research universities, foundations, social enterprises, non-profits, and other stakeholders.

The Way Forward

Thanks to President Obama's leadership, the Administration has taken large strides in developing and implementing an ambitious innovation agenda. The Recovery Act alone provides over $100 billion to support research and development and the deployment of advanced technologies such as clean energy, health IT, the smart grid, and high-speed rail. This commitment to investing in America's future continues in the President's most recent budget, with sustained support for research, entrepreneurial small businesses, education reform, college completion, and a 21st century infrastructure.

The Obama Administration believes that the America COMPETES Act should be reauthorized this year so that the Nation can continue to build on the achievements

of the original Act. I share the belief that the President and the Vice President hold, who supported the original COMPETES Act when they were Senators, that the COMPETES Act provides a valuable roadmap to guide Federal policies in innovation, competitiveness, and STEM education. We are supportive of this Committee's efforts to reauthorize this landmark act this year, and we very much look forward to working with the Committee to make the reauthorization a reality during this session of Congress.

The Administration is working with a wide range of stakeholders to identify the most promising ideas for implementing and further refining the Administration's innovation strategy. There are active inter-agency working groups on issues such as prizes and challenges, regional innovation clusters, research commercialization, spectrum reform, broadband, open government, and standards. The National Science and Technology Council is leading multi-agency research initiatives in dozens of critical areas such as aeronautics, genomics, green buildings, nanotechnology, quantum information science, robotics, and information technology. Through the President's Council of Advisors on Science and Technology, the Administration is able to receive high quality advice from the Nation's leading scientists, engineers and innovators on issues such as health information technology, advanced manufacturing, clean energy, and STEM education.

America has always been a Nation built on hope—hope that we can build a prosperous, healthy world for ourselves and for our children. These long-standing American aspirations depend critically on our far-sighted investments in science, technology and innovation that are the ultimate act of hope and will create the most important legacies we can leave.

The United States is still the land of the future. We have held that honor since this continent was discovered by a daring act of exploration more than 500 years ago. We have earned it anew with each passing generation because America's scientists, entrepreneurs and public officials have understood the importance of applying the power of American curiosity and ingenuity to the biggest economic and societal challenges.

I welcome any questions that the Committee may have.

Senator KLOBUCHAR. Thank you very much, Mr. Chopra. I really appreciate that, and thank you for that end, there. And I think we all share the same commitment. I just want to figure out how we're going to implement it, how we're going to get there, and——

Mr. CHOPRA. Amen.

Senator KLOBUCHAR.—you ended there, because you had to end quickly, about the innovation centers and encouraging this on a governmental level. I know China has instituted what they call an innovation policy. The Indian government is building industrial parks to spur innovation. What is our government doing to ensure that we remain competitive along those lines? What more can we do? I believe we're still the number-one innovator, but people are really catching up fast. And what should we be doing?

Mr. CHOPRA. Well, thank you very much. I believe the President's strategy sets the framework, Senator, on how we would attack this issue. But, if I were to highlight some key investment decisions that we're making, I would say, first and foremost, we're doing a significant job—you all, together with the administration—to make good on the America COMPETES commitment to double the core funding in our basic science and research activities: NSF funding, the National Institutes of Standards and Technology, and the work that's happening within the Office of Science at the Department of Energy. That investment decision, despite our tough economic climate, is going to sow the seeds for the next decade of economic growth. And I'm thankful that Congress has been supportive of that particular commitment.

In terms of capacity, I would say the single biggest opportunity that doesn't necessarily require a tremendous amount of invest-

ment is to strengthen and improve our capacity to move ideas—what we call "the lab gap," as my colleague Judy Estrin, one of the entrepreneurs in our society, has described to move ideas from universities to the private sector.

In many cases, this is a cultural and institutional challenge; that is, organizations that do a better job of identifying the relevance of a given research idea, and then introducing that idea through some prototype activities that don't cost a lot of money, to get them "cooked," if you will, in time for the private sector to pick them up, is actually an area where, if you get the culture right and you change some of the processes on technology transfer, you might actually see an increase in the return on very modest taxpayer investment.

To this end, we have an active request for information underway from the Administration—we called for this about 2 months ago—for the best ideas on how we can strengthen the cultural and institutional capacities at our Nation's Federal labs and universities. Secretary Locke and I are touring the country. We're holding four regional workshops identifying best practices, and we're hopeful that, by this fall, we'll put together a pretty aggressive package that will demonstrate, again, with limited to modest additional funds, in terms of university research activities, to actually shift some of these cultural norms.

There are areas—and we can talk at much greater length about some of the other activities that we're doing specifically in clean tech—where you might have more of a direct relationship to how other nations have taken on a more, vertical approach in a given area. I'm happy to discuss this if you'd like to go deeper there.

Senator KLOBUCHAR. What about commonsense innovation promotion, in terms of our regulatory agencies, the issue I raised, in specifics, with medical device, but that Senator Warner raised more broadly, just in general? And how do you make sure the agencies are doing their jobs, but also have an understanding of how we must be able to compete internationally against countries that have more streamlined processes, like in Europe?

Mr. CHOPRA. One of the reasons the President created the Office of the Chief Technology Officer was precisely to understand how these new capabilities actually influence a broader range of policy goals. And so, it is in that context, within a month of my confirmation that I had convened our first investor summit with the FDA, specifically on the topic, of biotechnology investments; and strategies that the FDA could embark upon, through a transparency initiative that is now seeing its way through on implementation, that would bring more visibility into the operations of the FDA, and has strengthened that relationship between the investor community, the entrepreneurial community, and the agency. I am convinced that there is more to be done in this area, and we are focused on continuing these industry collaborations, through both my office, and through Dr. Hamburg's office.

We are very focused on making sure that we see emerging capabilities—now, it strikes, in a couple of ways. There are traditional medical devices that are now taking more advantage of wireless capability. So, the intersection of information technology and traditional medical devices opens up new opportunities, but also creates

some challenges in the marketplace, in terms of, How does one manage this? On July 26 and 27, we're having a public forum bringing the FDA and the FCC together specifically around this issue, a topic that had been raised by Chairman Genachowski in the National Broadband Plan. So, I intend to bring leadership on issues like, How do you bring regulatory perspectives at the intersection of these disciplines, in addition to strengthening the transparency and the collaboration between the public and private sectors, so that we achieve the President's call—and your comments were rightly on point—for economic growth through investments in innovation?

Senator KLOBUCHAR. I appreciate that.

I'm going to turn it over to my colleagues, but I will emphasize, again, that image of those drummers at those Beijing Olympics, because it is getting louder and louder and louder. And I say this not only to you, but also to our own Congress, that we have got to unify and put some of the partisan politics aside and move on these innovation issues, to compete as a country.

And I'll turn it over to Senator LeMieux.

Senator LEMIEUX. Thank you, Madam Chair.

Mr. Chopra, thank you for being here today.

Mr. CHOPRA. My pleasure.

Senator LEMIEUX. I appreciate the work that you're doing on this very important issue.

I want to ask you a general question and then get in some specifics. This report, showing that we went from one to six, and then, you measured, it's really worse than that, because of the rate-of-change issues.

Mr. CHOPRA. Yes, sir.

Senator LEMIEUX. What do you think are the reasons that we had such a precipitous decline?

Mr. CHOPRA. I would certainly welcome Dr. Atkinson to provide his scientific and technological perspective. My humble opinion is that this has to be a priority of the administration. And I don't want to render judgments on any particular priority sets that have been there in the past, but, structurally, our President—this administration—has made this a key priority. He has created this team of individuals, and myself as Chief Technology Officer, where this is my job. My focus, day and night, is ensuring that we have the right policy frameworks that will promote the right investment decisions, where we make them, but, more importantly, that we've got the right interfaces between the public and the private sector to spur activity.

So, focus and leadership, I think, are a component of this.

Senator LEMIEUX. So, were we more——

Mr. CHOPRA. Dr. Atkinson might be more specific about investments in particular areas in education and——

Senator LEMIEUX. Were we more focused on this in the 1990s, in your opinion?

Mr. CHOPRA. I don't——

Senator LEMIEUX. Or was it the private sector that came forward and did this?

Mr. CHOPRA. I actually think that this is not an either/or. In fact, if anything, more research will suggest to you that, if you're an

early adopter of a capability set, having trust that the environment in which you're operating, that the product or services you're actually using will actually work—one of the benefits of having an FDA is that, if you're going to try a new drug, the American people have greater confidence that that drug should be consumed, because it's gone through a rigorous process. If you do it right, they actually can be synergistic; that is, the fact that we have an effective, functioning and working regulatory structure should open up markets of innovation, because you've created an environment where you have greater confidence—as the first mover, if you will—that when you take advantage of that new capability, that it's backed with some confidence.

I understand, in today's environment, given the Gulf Coast oil spill and some of the concerns we've had with the financial markets, people's faith in our ability to execute on this may be at risk. However, I do not believe this is an either/or proposition. I think if we get both right, we would see that rising tide lift all boats.

Senator LEMIEUX. Let me speak to you, if I can, specifically on some of the conditions that make innovation possible.

Mr. CHOPRA. Yes, sir.

Senator LEMIEUX. And one that I hear a lot about from businesses in Florida right now is a great concern, no matter what type of business they are, on certainty from their Federal Government, is the regulatory certainty or predictability. Because when things are unpredictable, businesses freeze up and tend not to act.

Another thing that's important for entrepreneurs is a low tax environment, and a predictability of tax environment. We're about to have a debate, in the coming months, about capital gains tax.

Mr. CHOPRA. Yes.

Senator LEMIEUX. And it's set to increase from 15 percent to, potentially, 20 or more, all the way up to 39 and a half. Do you have an opinion, does the Administration have an opinion, on capital gains tax, where it should be in order to promote as much innovation as possible?

Mr. CHOPRA. I don't have an opinion on the right capital gains tax rate, but I do believe this President has been explicitly clear. Making the R&E tax credit permanent has been a priority of this Administration. As part of the health reform bill, we included a billion dollars in the therapeutic tax credit, precisely to offer tax credits, and, in that case, grants, for those companies that don't yet have profitability—a tax incentive, if you will—to promote innovations in new therapies. We've been supportive of those activities. The President has been very clear about areas like that R&E tax credit.

So, you raise a very important topic, and I would certainly look forward to that conversation. My colleagues at the Treasury Department and the National Economic Council are clearly engaged on those issues more specifically.

Senator LEMIEUX. Right.

Mr. CHOPRA. My focus is ensuring that we have the right technological foundation for those discussions.

Senator LEMIEUX. But, as a business person, a person who's the Chief Technology Officer——

Mr. CHOPRA. Yes, sir.

Senator LEMIEUX.—Capital gains tax is important. And obviously, it has to be something in order to generate revenues and to be a fair and equitable part of our tax system. But, a lower capital gains tax is going to provide for more incentives for innovation, is it not?

Mr. CHOPRA. Frankly, my priority is promoting top-line growth. If you were to interview the top 20 CEOs, asking where the growth sectors are in the economy, I think they would say opening up overseas markets—because of the growth sectors that are there, would rank as a high priority. I think if you were to suggest domestic markets, the healthcare sector and the energy sector—if we get the healthcare sector and energy sector right—with respect to their willingness to embrace innovation, you might see a tremendous opportunity.

Just as an example, as Madam Chairwoman described, venture capital has seen a bit of a decline, but if you looked at the 2009 statistics compiled by the National Venture Capital Association, healthcare IT venture capital, up 37 percent, while overall venture capital saw a decline by roughly 31 percent. Those are their numbers, not ours.

I would argue that that's, in part, because of the focus on top-line opportunity. The President's commitment to the Recovery Act, on promoting the adoption of electronic health records, has had an impact, I believe, that has created the market conditions for more venture capital investment and more opportunity.

If sectors of the economy that have not benefited from the Information Technology Revolution find opportunities to do so—because we get the rules right on cybersecurity, because we think more thoughtfully about how to introduce health IT and the Smart Grid—we believe that we will unlock tremendous opportunities for economic growth, beyond any conversation that one might have on tax policy.

That's my position and the thing that keeps me up at night as I serve our Administration.

Senator LEMIEUX. My time is up, but we may have some time for some more.

Senator KLOBUCHAR. OK.

Senator Warner.

Thank you.

Senator WARNER. Thank you, Madam Chair.

Let me start where my colleague Senator LeMieux mentioned. I believe tax policies ought to encourage long-term hold, early-stage capital formation. And I personally believe making sure that we've got as low as possible capital gains rates make sense, although I would argue that it's not always a direct correlation. I would argue that, during President Bush 41 and President Clinton, when capital gains rates were actually higher than they had been in the last decade, there was more innovation created.

Now, we've still got to get tax policies right. And some of us up here have had some concerns with certain pay force recently that might have even tripled the rates on the venture community that is about early-stage capital formation, in terms of current legislation. I've been trying to work through some of that.

But, we've got that double-headed whammy right now, as we want to make America business-tax competitive and business-tax friendly. I personally believe not only should the R&E tax credit be made permanent, but it should be raised from 14 percent, hopefully up to 20 percent, to be competitive with other OECD countries. But, you can't do it in a revenue vacuum at the same time dealing with—the other looming challenge we've got out there, the deficit. A challenge I try to make when I see tech companies is, I'll lead that fight, but they should not carp when they raise personal taxes on people like me, and them, back up to the rates during President Bush 1 and President Clinton, because you've got to even it out somehow. You can't get this fixed on the deficit side, on only one side of the ledger.

I appreciate your comments on the regulatory efforts. And it's tough, because we've seen, with the failure to regulate, at times—the Gulf, between Wall Street and main street—but, I hope we'd see from the Administration a little more clarity on how we can use transparency——

Mr. CHOPRA. Yes, sir.

Senator WARNER.—as a way to streamline the regulatory process. If you look at the business functions, there's a lot quicker movement from idea to implementation in the business side than there has been on the government side. And I would love to—you don't have to answer today—but, I would like to see some real deliverables on what you've been working on——

Mr. CHOPRA. Yes, sir.

Senator WARNER.—and specific examples, whether it's FDA, whether it's EPA—other areas, where—in this, I think, preeminent need to keep our innovation lead, we're going to make it easier to get ideas into the business mode and operational mode. Number one.

Mr. CHOPRA. Yes.

Senator WARNER. Number two, I hope—and I appreciate the fact that you mentioned Stanford as one of your case studies—you know, candidly, regardless of what's going to happen, Stanford, MIT, and a few other top-tier universities are going to do fine. I wish we could have cited an example at the University of Minnesota, University of Miami, University of Florida; VCU, in Richmond; and trying to make sure that we have a broader breadth of participation from our university sector, other than just the regular suspects. Because, candidly, the same idea we've had for years, has been the top ten universities say, "Give us more money, and trust us." And it's had some mixed results, but not necessarily in a financially constrained area, as much as we need.

I'd also like you to see—and perhaps you can answer this so I can actually get an answer to the question instead of me yakking on—in the stimulus, there was over $100 billion——

Mr. CHOPRA. Yes, sir.

Senator WARNER.—that falls into different kind of innovation buckets, whether it is, in NIH, areas around education—or, around energy, Smart Grid, healthcare IT—I think it would be very helpful—as most of the American public still questions, I view, the stimulus was, while not pretty, necessary—it would be very helpful to us, as we start to see, What are the deliverables and what are

the metrics that we can measure from that $100-billion investment? Do you want to take that one?

Mr. CHOPRA. Let me take that one first, Senator Warner.

We are absolutely committed to telling that story right. And I'm confident, in the not too distant future, we'll have a more thoughtful, complete inventory of——

Senator WARNER. It would help, since a third of that was tax cuts, and nobody in Virginia knew we gave them a tax cut, either, so it really——

[Laughter.]

Senator WARNER.—you know, we're almost 2 years in—or, a year and a half into this—it would really help—the sooner the better on this, but——

Mr. CHOPRA. Particularly on the impact on innovation, if I may be very specific, we have been very active in tracking the results of our recovery investments. We've actually even introduced some innovations. One of the pilot projects we initiated, called STAR METRICS, was an attempt to automate how our investments in universities actually translated into job creation more easily, more accurately, and more comprehensively than perhaps the traditional method of tracking some of these statistics in the past.

So, my confidence is that we'll respond very shortly to you——

Senator WARNER. When?

Mr. CHOPRA.—on it. I can't say exactly when. The——

Senator WARNER. Sixty days?

Mr. CHOPRA. Oh, definitely within 60 days. That's an easy one. Yes. Done. In less than 60 days, you will have a better, more thoughtful report on the impact the Recovery Act has had on the innovation investment.

Senator WARNER. My time has run out, but I just would like to make one other point.

Mr. CHOPRA. Yes, sir.

Senator WARNER. I've had conversations with your colleagues at Treasury on this, but I think it is a very big issue, this question of early-stage capital formation. And as we kind of sort through the Wall Street reform and try to get it right, that we think about policies, not just for that earliest-stage startup enterprise, which the President's been supportive of, but on a broader basis, how we encourage early-stage capital formation in this country. And my hope would be that there are voices like yours and others from the tech side and the innovation side who are kind of making this case inside the Administration.

Mr. CHOPRA. Yes. If I may, just for a moment—I do want to be respectful of your time—but, one of the responsibilities I have as Chief Technology Officer is to lead interagency activities, to make sure that we have all the voices at the table. As one example—we've launched an Innovation and Entrepreneurship Working Group, with over a dozen or so Federal agencies, and we have a specific team dedicated to access-to-capital issues.

And part of the goal, Senator Warner, is that there are policy changes we can make within the current administrative processes that we have, that can be improved, that can deliver results sooner, and then there are broader questions about how we work with you all on formal changes to the law, where appropriate.

We're looking at any and all of those options, and I look forward to coming back and sharing with you the results of that work.

Senator KLOBUCHAR. Very good.

Senator Udall.

STATEMENT OF HON. TOM UDALL,
U.S. SENATOR FROM NEW MEXICO

Senator UDALL. Thank you, Chairman Klobuchar. And I appreciate you doing this hearing, and chairing it for us.

Mr. Chopra, last year, Congress mandated that the FCC create a National Broadband Plan to address one of the most significant infrastructure challenges of our time: making broadband available to all Americans. And in a rural State like New Mexico, we really need that to happen.

A witness on our second panel points out that other countries have created national innovation plans to identify ways that their policies can better promote innovation and entrepreneurship. For example, could OSTP help review current policies that block innovation, as well as recommended policy changes that promote innovation and entrepreneurship? And could OSTP work with the Department of Commerce and other Federal agencies to develop such a national innovation plan?

Mr. CHOPRA. Thank you very much for your kind question. We are continuing to build upon the President's strategy for American innovation that was released last year in the fall, to continue with the improvement of that plan.

Now, the word "plan" is one of those that requires a bit of clarity, in terms of, What do you mean by "plan"? And Senator Warner had some comments about specific metrics deliverables and timelines. I think we will continue to iterate on what we believe to be a national plan that is within the constraints of our Nation's commitment to mostly private-sector entrepreneurship and innovation, more so than a top-down industrial model.

Whatever the case may be, we're always open to listening and understanding strategies that you think would be more productive, and we are committed to making sure that we've got a harmonized approach across the Administration.

I would suggest that there are three things that are top of mind in the question that you just asked. Are there policy barriers that we should be removing, administratively?

Senator UDALL. Right.

Mr. CHOPRA. I think this gets to the question that the Chairwoman had asked earlier about, How are we creating more certainty in the market? We're certainly open to those, inventorying them, and we're hoping to take action. We've taken some action here and there. We'll take more as the months go.

Second, when we do make investments, are we getting the right return on investment? I think the spirit of greater accountability and transparency for the dollars spent has been a commitment of this Administration. OMB Director Peter Orszag mentioned, earlier in June, that under my leadership and our CIO, Vivek Kundra, we'll be developing an R&D investment dashboard to bring greater transparency into the monies we're spending, so that funds can be

allocated to the highest-return areas; and not just single-dimension definitions of "return," but, more broadly, in terms of impact.

And then, third, I would argue that there may be opportunities for new investments, more platform investments, that have the ability to achieve a much greater degree of innovation. A simple example there: We launched a website, *data.gov,* a year ago, that now has over a quarter of a million data assets that are available for the public, free of charge—and entrepreneurs, in particular—to consume that data and launch new businesses.

Secretary Sebelius, in March, said, "In 90 days, I want to see how the entrepreneurial ecosystem responds. Here are thousands and thousands of pieces of health data. Go help people improve the quality of healthcare in their local communities." And a dozen entrepreneurs showed up, 90 days later, at the Institute of Medicine. They weren't paid, there was no law; there was just a call for action. And literally they demonstrated new and creative applications that would move the needle.

So, in short, we are very focused on stopping policies that are inhibiting innovation, getting the investment portfolio right, and thinking about platform investments that have much greater return if they were done in a more thoughtful and collaborative way.

Senator UDALL. Thank you very much for that answer. And I think that's exactly the kind of thing we need to be doing with innovation with broadband. And then I think you also mentioned, in your testimony, about modernization of the Nation's electric grid as——

Mr. CHOPRA. Yes, sir.

Senator UDALL.—a vital component of efforts to build a low-carbon economy. And so, we develop a comprehensive policy framework for a Smart Grid—we need the same thing there, the same kind of thinking. So, thank you.

Mr. CHOPRA. A brief answer: I announced on June 8, at Brookings—that we're forming a National Science and Technology Council Committee focused on the Smart Grid, led by myself and Phil Weiser, who works in the National Economic Council. We're holding a forum, a public forum, at Brookings, in mid-July, and we're going to publish a strategy on this issue by the fall. We believe, very emphatically, that the Smart Grid has tremendous opportunities for both energy efficiency improvements as well as economic growth from new entrepreneurial companies. In fact, a Colorado-based company, Tendril, is actually our first deployment of the Smart Grid in the NSTAR implementation in Massachusetts. Three-thousand homes are going to get a little widget that would allow them to track their real-time energy consumption information and to build all these innovative applications so they can be told when they might want to consider reducing the temperature, and so forth, in their home.

Anyway——

Senator UDALL. That's great.

Mr. CHOPRA.—thank you so much for the question.

Senator UDALL. We look forward to seeing that strategy.

Mr. CHOPRA. Yes, sir.

Senator UDALL. Thank you.

Senator KLOBUCHAR. Very good.

I wanted to follow up. I know, in the President's State of the Union Address, he focused—which I was glad that he did this—on doubling the number of exports. Could you talk about where that is right now? Senator LeMieux and I have a bill, which I believe Secretary Locke supports, to help with the Foreign Commercial Service, to make sure that the Commerce Department and others are helping, in any way, our small and medium-sized businesses.

We have some amazing success stories in my State—5 employees up to 55; 10 employees up to 77—because they simply actually called the Federal Government—these are conservative businessmen, who never believed it would be true, but said, "We have this product." "Can we sell it in Turkey? Can we sell it in Morocco?" And they actually got help, and help get the customers vetted and their businesses ballooned, and in a very good way.

What's being done right now with the export issue?

Mr. CHOPRA. This is one of Secretary Locke's top priorities in his commitment to President Obama. We have a few key strategies in motion. There's the blocking and tackling, as you've said, getting the international trade team much more focused, not just on promoting exports from our large corporations, but to be very focused on the small business owner. There are so many small business owners today who export to one country. And, as Secretary Locke said to the President, "If we just get them to export to a second or third, precisely the kind of economics you're describing will take hold." So——

Senator KLOBUCHAR. Yes, I think——

Mr. CHOPRA.—blocking and tackling——

Senator KLOBUCHAR.—60 percent actually only——

Mr. CHOPRA. That's right.

Senator KLOBUCHAR.—export to Mexico——

Mr. CHOPRA. To one.

Senator KLOBUCHAR.—or Canada.

Mr. CHOPRA. You're absolutely right.

So, number one, blocking and tackling, get the agency focused on providing those support services to all businesses.

There's obviously a great deal of work in transparency and what we can do to bring more information to business owners.

And, last but not least, we're very much focused on intellectual property enforcement, and a global strategy in that regard. In fact, I believe, 3 hours ago, the Vice President announced a strategy to promote intellectual property enforcement. And an important component of that is our commitment to promoting exports, precisely because of the fact that we do believe that there needs to be much more aggressive activity to support American business interests abroad, because so much of our economy's growth has been built on the foundation of intellectual property in this country.

So, on all fronts, we are making progress, Senator. And if there are specific questions, I'd be happy, in the record, to make sure I get them answered for you.

Senator KLOBUCHAR. I had raised the issue of people coming from other countries to study at our universities, and a number of us have been working on at least this concept of allowing people to stay, instead of putting up a "Do Not Apply" sign after they graduate. Could you talk about the role that could play in our com-

petitiveness? And to what extent should we examine our H–1B visa program for people? Again, I've just heard many stories, from my State, of companies who try to bring someone in. They can't. They don't meet the game of Russian roulette over who gets in and who doesn't, and then they end up contracting with them anyway. And then we don't get the tax revenue. So, could you talk about how we could improve that process?

Mr. CHOPRA. Well, as you know, this is an area where the President has been pretty clear about his support to ensure that we have a thriving innovation economy. And a great number of our entrepreneurs and innovators, as research will show you, do have their origins in other countries. It's actually a personal issue for me, as well. My father holds three patents, and he came to this country from India, and we're grateful for the chance to have immigrated here.

This President is committed, as you know, to a comprehensive approach on immigration reform. So, the strategy has been very clear from the get-go. This issue is absolutely important. And as he and the team work closely with you and Congress on finding a strategy forward, we are very supportive of ways in which this particular challenge can be addressed.

Now, in ways small and modest, we are making administrative changes to make it easier. We've simplified scientists who are visiting this country from overseas, for the visa application process, so there's a collaboration, between our science team and the State Department. It's not a significant victory, in the sense that we haven't solved the immigration problem, but we've made that a little bit easier.

Just this past month, the U.S. Citizenship and Immigration Service, under Ali Mayorkas's leadership, has convened a summit, had a public hearing, if you will, on the discussion of the investor visa; that is, the EB–5 visa. He opened it up for conversation, and a number of folks participated in that call, calling for strategies to strengthen and improve the investor visa to try to get to a place where more people might take advantage of it.

So, your point is well taken. You may have seen, the President had an Economic Recovery Board meeting that was publicly aired via webcast, and you heard the President's key economic advisors specifically say to him, "We should be stapling a green card to every graduate of our Nation's leading research universities." The President acknowledged that comment and, again, reiterated his support, as part of a comprehensive approach on immigration reform.

Senator KLOBUCHAR. Thank you.

Senator LeMieux.

Senator LEMIEUX. Thank you, Madam Chair.

I want to speak for a moment about exports, and follow along the line of questioning that——

Mr. CHOPRA. Yes, sir.

Senator LEMIEUX.—Senator Klobuchar was on. And part of a successful export strategy is to get these free trade agreements passed. We have pending free trade agreements with Colombia, South Korea, and Panama. I believe the Colombian agreement was negotiated in 2006. And this is perhaps our greatest ally in the

Western Hemisphere, certainly in Latin America. And our competitors—Canada and the European Union—have already approved these agreements. So, where are we on submitting those agreements to Congress and getting their approval?

Mr. CHOPRA. I don't have any particular information on the status of the free trade agreements, but for the President's commitment as he said as part of his pronouncements on our commitment to exports, that we will move forward on a number of agreements. And I will defer to Ambassador Kirk to provide specifics about where those agreements are, as I do not have that information with me.

Senator LEMIEUX. I want to, if I may, Madam Chair, ask a follow up question, or a following question, which is a little bit off of our mission today. But, it occurs to me, as the chief technology officer of the United States——

Mr. CHOPRA. Yes, sir.

Senator LEMIEUX.—that this is something that you might be able to be helpful with. We talk a lot about measurement and metrics. And certainly, technology has given us the ability to that, internal to government. One——

Mr. CHOPRA. Yes.

Senator LEMIEUX.—thing that I have proposed—you were talking about Secretary Sebelius making the call to action on——

Mr. CHOPRA. Health data.

Senator LEMIEUX.—health data, healthcare records—one thing that I have proposed is using performance metrics to help catch Medicare fraud. And there's an industry that has a very low instance of fraud, which is about the same size as the healthcare industry, and that's the credit card industry. They use performance metrics, and they use predictive modeling.

Mr. CHOPRA. Analytics.

Senator LEMIEUX. So, when you use your credit card someplace, you're out of town, you get a phone call from——

Mr. CHOPRA. Yes, sir.

Senator LEMIEUX.—your credit card company, saying, "Is that you? Did you really authorize that transaction?" If you don't tell them, "Yes," they don't pay. And that's how they stop fraud before it starts.

We've got a proposal, Senate bill 2128, that I'm currently working on with some of my colleagues—Senator Baucus, Senator Whitehouse—to try to get accomplished. But, is—the reason I raise the question is, in your role, have you been asked to look inward on the government——

Mr. CHOPRA. Absolutely.

Senator LEMIEUX.—to see that we can use technology to create efficiencies and stop the waste, fraud, and abuse?

Mr. CHOPRA. Yes, sir. I work closely with the President's Chief Performance Officer, who's the Deputy Director for management in the Office of Management and Budget, and, the Chief Information Officer, who's also in the Office of Management and Budget. Together, the three of us meet weekly on strategies to improve the performance of our Nation's agencies.

In this particular example, I am very focused on ways we can bring emerging technologies and technologies from other industries

into the government itself. While not my responsibility for monitoring the implementation of the Recovery Act, which the inspector-general community, took advantage of one of those emerging technologies that had been in use in our intelligence communities, advanced analytics, the predictive work that you're describing—to basically mash up as much data as possible to look for patterns that aren't obvious to an individual analyst. And I'm confident that the results we're seeing, which are, at least to date, low rates of fraud in the Recovery Act, in part are because we've got this very sophisticated tool.

The President has been very clear that he wants the best tools going after Medicare waste, fraud, and abuse. We are going to—I don't know if we've announced it yet, or we soon will be announcing—a similar commitment to bringing those advanced tools, specifically going after Medicare waste, fraud, and abuse.

There is no doubt that there are lessons to be learned from how the private sector has adopted information technology and how we can improve the government. One comment here. We held a forum on modernizing government. We had 50 or so CEOs from companies, big and small—Microsoft to startups—and the overwhelming message that we heard is that we have a technology gap between the way we live in our private lives and the way our government uses technology in its professional setting. And we are absolutely focused, like a hawk, on closing that information technology gap. In fact, we've been beginning to release strategies to that fact across this month. Peter Orszag gave a speech on this issue—I think it was June 8—where he announced this broader vision. And we'd be happy to make sure that you're provided a copy of that document.

Senator LEMIEUX. I would appreciate that.

Mr. CHOPRA. Yes, sir.

[The information referred to follows:]

REMARKS BY PETER R. ORSZAG—CENTER FOR AMERICAN PROGRESS

June 8, 2010, Washington, D.C.—*As Prepared for Delivery*

Thank you, Tom, for that kind introduction. And let me thank John Podesta and the Center for American Progress for inviting me to speak here today.

Many of you may not know that my first experience working for the Federal Government occurred when I was a senior in high school, when I got an internship with a freshman Senator that I never heard of from a state I had never been to.

I was fortunate that Spring because that office—Senator Daschle's office—was very much like the man who stands before you today: open to debate and good ideas, inclusive, and kind.

My workspace has since been upgraded from Tom Daschle's mailroom to an office in the Eisenhower building. And when I moved into that office, I must admit that I took down a picture of President Eisenhower and replaced it with a portrait of Alexander Hamilton.

It's interesting that in the first line of the very first of the 85 *Federalist Papers*, Hamilton laid out why the United States needed a new form of government. It wasn't because the Founders had second thoughts about the basic idea of democracy. Instead, it was, as he put it, because of the "unequivocal experience of the inefficiency of the subsisting Federal Government."

There it is in the first line of our founding narrative: a practical concern for the delivery and performance of the Federal Government.

And it is that enduring struggle to create a Federal Government that is of, by, and for the people—and that accomplishes those goals in a way that is efficient and effective—that I want to discuss today.

Too often in Washington, we spend more time developing, debating, and deciding which policies to pursue than we do actually figuring out how to implement them.

But in reality, execution matters—and matters a lot.

Take the Recovery Act as an example. One of the largest pieces of domestic legislation in recent memory, it was designed to jumpstart economic activity and prevent another Great Depression, and it is as complex as it is large in dollar amount.

The evidence strongly suggests that the Recovery Act has been effective in reviving economic growth. We have seen, for example, a swing from an average GDP decline of 5.9 percent on an annualized basis at the end of 2008 and beginning of 2009 to an average growth rate of 4.3 percent a year later, the largest one-year swing in GDP growth in three decades.

And what has been most striking is that for an initiative this large, we have not seen any substantial incidences of fraud and abuse.

This, I believe, is to the credit of "Sheriff Joe"—our Vice President—who has made it his mission to make sure that the Recovery Act is implemented swiftly and effectively.

Just as the dog that doesn't bark doesn't get any attention, effective implementation does not garner the headlines. But it is central to making government work better, reducing waste, and actually delivering the services people want and need.

That is why from curbing the use of no-bid contracts to reducing improper payments—from changing how we hire Federal workers to how we purchase and use information technology, the President has undertaken a far-reaching effort to modernize and reform government.

And we are lucky to have Jeff Zients serving as the Nation's first Chief Performance Officer to oversee this initiative.

The effort is necessary for three reasons.

First, we have massive national challenges that require national responses: laying the foundation for long-term economic growth, bringing about a clean energy economy, improving the quality of and reducing the costs of health care, reforming and improving our schools, protecting our homeland, and the list goes on and on.

Second, just as the American people *expect* more to be done, they are skeptical that it can be done.

According to the Pew Center, from 1987 to 2007—with one exception immediately after the 9/11 attacks—about two-thirds of Americans believe that "when something is run by government it is usually inefficient and wasteful."

In effect, Americans have determined that their government cannot deliver what they want, an unsustainable fact for the life of our democracy.

Third and perhaps most importantly, as stewards of the American public's tax dollars, we cannot afford to waste money on programs that do not work, that are outdated, or that are duplicative of one another.

Right now, there are over 110 funded programs in Science, Technology, Engineering and Mathematics education in 14 departments and agencies across the Federal Government; over 100 programs that support youth mentoring scattered across 13 agencies; and more than 40 programs located in 11 departments with responsibility for employment and training.

This redundancy wastes resources and makes it harder to act on each of these worthy goals. That is one reason why the Administration proposed approximately $20 billion of terminations, reductions, and savings in both the FY 2010 and 2011 budgets.

And while recent administrations have seen between 15 to 20 percent of their proposed discretionary cuts actually enacted, we worked with Congress to enact 60 percent of proposed discretionary cuts for FY 2010.

This type of redundancy and waste is also why the President 2 weeks ago asked Congress for expedited rescission authority so Congress can act quickly and cleanly to remove unnecessary and wasteful programs.

To be sure, reducing this waste will not close the significant budget gap we face. But that fact does not absolve us from the obligation we have to use funds wisely.

What is driving these trends and the skepticism so many of us have about government?

One important reason is that over the years, Americans have seen huge advances in efficiency and technology both at work and in their daily lives.

They have witnessed the movement from one-size-fits-all, mass production and secretarial pools to the age of just-in-time, customized manufacturing and instant communications. Organizations outside government have experienced impressive advances in productivity and have become more responsive to their customers.

The government, however, has not kept pace. Let's look at the facts.

Public-sector productivity growth matched the private sector's until about 1987. But something changed in the late 1980s. From 1987 until 1995, private-sector pro-

ductivity rose by an average of 1.5 percent a year. Meanwhile, the public sector's productivity rose by only 0.4 percent per year—or about one-third as much—over roughly the same period.

At that point, reliable data on public-sector productivity are not available because the Bureau of Labor Statistics—paradoxically, as part of a cost-cutting effort—stopped collecting the numbers.

The best analysis we have, from the McKinsey Global Institute, suggest that since 1995 it appears that the public sector continued to fall behind the private sector which saw productivity surge during that period.

Some of this increasing gap has to do with advances in management techniques in the private sector. Some, undoubtedly, has to do with the challenges the Federal Government has in attracting and hiring top talent. Keep in mind that the average time it takes to hire a new Federal employee is 140 days—and by that time, many of the best candidates, understandably, have gone elsewhere.

But I believe that the biggest driver of this productivity divide is the information technology gap.

At one time, a Federal worker went to the office and had access to the most cutting-edge computer power and programs. Now, he often has more of both in a device clipped to his belt.

Closing the IT gap is perhaps the single most important step we can take in creating a more efficient and responsive government.

Indeed, the IT gap is the key differentiator between our effort to modernize and reform government and those that have come before.

While it would be better if we did not find ourselves in this position, note that because the gap is so big, the potential upside is substantial. Our historical shortcomings in IT may ironically give us a "late-mover advantage," by allowing us to leapfrog costly, less developed technologies and go directly to the less expensive, more powerful ones.

How big is this IT gap?

It is hard to quantify, but anecdotally the data are telling.

Let's consider the divergence in data center usage. In the private sector, IBM has reduced the number of data centers it uses from 235 to 12. Hewlett-Packard has consolidated 14 data centers into one, reducing energy usage by 40 percent.

What about the Federal Government?

Since 1998, we have gone from 432 data centers to more than 1,100.

Or look at how the Federal Government has tried to introduce systemic technological improvements to its operations.

In the conversations we had with CEOs at our modernizing government forum in January, most told us that they terminate a substantial number of bad IT projects soon after they start. High-performing companies kill roughly one out of every three IT projects in their first 6 months. The Federal Government, by and large, terminates almost none.

For example, the Census Bureau awarded in 2006, a $595 million contract to develop a handheld computer for census workers to use this year. Two years and $600 million later, the project was canceled with nothing to show for it.

And census workers out there today still use pen and paper.

Or as the President pointed out before, the Patent Office receives more than 80 percent of patent applications electronically. That's great.

However, these applications are then manually printed out, re-scanned, and entered into an outdated case management system. The average processing time for a patent is roughly 3 years.

And this is the agency that interacts with the most creative and innovative individuals and companies in our country.

Clearly, we have massive room for improvement. Pursuing that improvement and closing the IT gap will help us create a government that is more efficient and less wasteful, and that is more open and more responsive to the American people.

So what are we doing?

First, we're using IT to identify and cut waste.

Take the dashboard concept—a graphically clear, data-rich web portal that enables a manager, and actually any member of the general public, to see how money is being spent.

Our IT Dashboard now provides a transparent look into the approximately $80 billion a year the Federal Government spends on IT. By using the dashboard, the VA has been able to identify 45 IT projects that are at-risk, eventually terminating 12 of them.

This same concept is being used by the Centers for Medicare and Medicaid Services with its dashboard to track inpatient hospital spending and how much Medicare

is spending on other payments to providers for medical education, treating low-income patients, and operating in a high-cost region—to name just a few.

We also are using IT to increase data-sharing among agencies to reduce the $100 billion in improper payments—payments that go to the wrong person, for the wrong amount, or at the wrong time—each year.

And we're doing that by expanding recapture payment audits, bolstering internal control methods, and creating online dashboards of key indicators and statistics about improper payments—so the public can hold agencies accountable for how their money is being spent.

Similarly, as part of the Administration's effort to save $40 billion in contracting by 2011—a goal we are well on the way of reaching—we have launched the so-called FAPIIS system, which takes data from government contractors on things such as how they did their job and if they were suspended or debarred—and combines them into one database that contracting officers can access before making a decision.

This will dramatically reduce the chance that an under-performing contractor with one agency will keep winning business from another.

Second, we are using IT in our efforts to boost the efficiency of government operations.

I mentioned earlier the growth in the number of Federal data centers, which runs counter to the movement in the private sector toward reducing the number of data centers and moving to cloud computing in which applications and data are centrally housed.

Through our Cloud Computing Initiative, we are just beginning to take steps toward the cloud. And this holds substantial promise to save money on IT infrastructure, increase collaboration, and boost productivity.

Third, in addition to identifying and rooting out waste, we can use information technology to make government more open and responsive—delivering services in ways that are convenient and cost-effective.

In almost every facet of one's daily life, you can use online and mobile devices—whether it's managing your money, paying a bill, buying a birthday gift, or arranging your own travel.

We need to bring that kind of convenience to government services.

That's why the Department of Homeland Security added an online tracking service for visa and citizenship applications—replacing the letters mailed back and forth when people wanted an update on their status.

And it's why the Social Security Administration is implementing an idea that we got through our SAVE Award process from a front-line worker in Alabama to allow people to make appointments online to see a Social Security caseworker, freeing up this personnel to actually help people.

Another way to deliver better services is to empower people directly with the information they need to serve themselves.

As part of our Open Government Initiative, we have unlocked the valuable Federal data that the government has—and put it out on data.gov—so that it can be leveraged for wider and greater use.

In just one year, *data.gov* has grown from 47 datasets to more than 270,000. This information can be used by the American people directly to learn about things such as the safety ratings of children's car seats or the safety of different work places.

And the data are increasingly being used by developers to build new tools to help Americans in their daily lives.

Let's take *FlyOnTime.us,* for example.

This application takes data from the Bureau of Transportation combines them with weather information and user-generated content about airline security lines—such as "tweets" from people waiting in those lines—to give travelers an accurate look at travel conditions.

In the months ahead, we will be looking to unveil more of these technology-driven solutions that bring the public sector more in line with the private when it comes to customer service.

That is the promise of closing the IT gap: increasing productivity and responsiveness; efficiency and customer service.

And that brings me to a final point: these improvements will help agencies meet what are increasingly tight fiscal constraints.

As many of you know, in this year's Budget, the President proposed a three-year freeze on non-security discretionary funding, saving $250 billion over the next decade.

This spending restraint complements other measures in the Budget that, together, produce more deficit reduction over the next 10 years than any Budget that has been proposed in over a decade.

In his State of the Union address, the President was abundantly clear to Congress that he will use the veto pen to enforce this freeze.

And in the Budget guidance for Fiscal Year 2012 issued to agencies this morning, that seriousness of purpose was underscored yet again.

We are asking each agency to develop a list of their bottom 5 percent performing discretionary programs, as measured by their impact in furthering the agency's mission.

In addition, to ensure that we can meet the President's absolute insistence on a freeze for non-security agencies while funding priority areas, we are asking non-security agencies to specify how they would reduce their budgets by 5 percent which will give us the ability to achieve the overall non-security freeze even while meeting inevitable new needs and priorities.

The reform efforts I outlined above should make it easier for agencies to identify their laggard programs and live within the three-year freeze.

Ultimately, our goal is not to cut for cutting's sake, but to modernize and reform government, to empower people with the information they require to make choices about what's best for them, to make their voices heard by government officials, and to give the American people the data they need to bring about change.

The bottom line is that IT can help us achieve this in a government that is increasingly complex, serving a Nation of 300 million people.

As a professor of political science at my alma mater noted: "There is scarcely a single duty of government which was once simple which is not now complex; government once had but a few masters; it now has scores of masters."

Those words were written by Professor Woodrow Wilson—in 1887, before he was the President of Princeton, and well before he was President of the United States. And they are no less true today than they were more than a century ago.

The lesson is: implementation matters. And it is our duty to continually strive to be prudent and productive stewards of tax dollars, creating a government that is efficient and effective in service of the American people.

Thank you, and I'd be delighted to take your questions.

Senator LEMIEUX. And I would commend you to look at this, Senate bill 2128, which seeks to accomplish this for Medicare. There's estimates that we could save $20 billion a year——

Mr. CHOPRA. Yes, sir.

Senator LEMIEUX.—by using predictive modeling.

Mr. CHOPRA. Absolutely. We'll look at it. Thank you——

Senator LEMIEUX. Thank you very much.

Mr. CHOPRA.—sir.

Senator LEMIEUX. Thank you, Madam Chair.

Senator KLOBUCHAR. Senator Begich has arrived.

STATEMENT OF HON. MARK BEGICH, U.S. SENATOR FROM ALASKA

Senator BEGICH. Thank you, Madam Chair. I'll just be brief.

You may not be able to answer these—but this is kind of a broad question, which I think I know the answer to, but I really want to hear you say it.

Mr. CHOPRA. Sure.

Senator BEGICH. With regards to patent protection for folks that are creating and being innovative and so forth, we would rate ourselves, in this country, where in the scale of patent protection?

Mr. CHOPRA. Well, Can I give two grades? I would say that the quality of our patent review process is pretty high. On a scale of 1 to 10, maybe it's an 8 or a 9, in terms of the competence of the agency to actually render judgment on high-quality patents. But, the process and the performance of the agency, in terms of its throughput, is far lower. To be kind, maybe it's sub–5, maybe 4, maybe 3. The backlog today is well over 3 years. We have circumstances where information comes into the Patent Office; in

some cases, it's in electronic format, in other cases, it has to be converted from electronic to be rekeyed in, because database A doesn't talk to database B. So, to the extent with which you would like to see an improvement—I believe Senator Warner made a comment earlier—you guys are engaging on the discussion of patent reform, but I believe there's bipartisan—and I don't want to speak for you——

Senator BEGICH. Right.

Mr. CHOPRA.—but I believe there's bipartisan commitment to just cleaning up the operations themselves so that we can strengthen and improve the capacity of the office.

Senator BEGICH. Let me ask——

Mr. CHOPRA. Yes, sir.

Senator BEGICH. That's part of the question, but the other part is, If I create something—where would you want to patent your product? What country?

Mr. CHOPRA. Boy, that's an interesting question. I haven't given that much thought. I would still presume that patenting in the United States is still a very powerful asset to—I mean, so much of our economy is borne on patent-generating—patented products and services. There are some case examples. I believe the Chairwoman highlighted a few—where people are beginning to take their innovations overseas. But, I would argue that it still makes the most sense in the world to patent your invention here in the United States, and that—we have pretty good collaboration across the world's patenting regulatory bodies, if you will, to work together on a streamlined approach to making sure that that application actually can be filed around the world.

Senator BEGICH. I appreciate that; I just wanted to get a little discussion; I know it may be partially in your field—but, here's my question——

Mr. CHOPRA. Please.

Senator BEGICH.—in the broader sense, and maybe more of a comment. So, if you want to comment on it, that's great.

Mr. CHOPRA. Sure.

Senator BEGICH. Companies—and it goes to, I think, what the Chairwoman was getting to, in a different way, or augmented to what she was talking about; and that is, people patent here, but they manufacture elsewhere.

Mr. CHOPRA. That's what she had made the——

Senator BEGICH. OK?

Mr. CHOPRA.—case for.

Senator BEGICH. Do you, or does someone in the Federal Government, have some analysis that says, here, in the last—pick a period of time—products that have been patented, that have been developed—produced overseas, but, at times, those same companies use our patent law to protect themselves for those products they manufacture overseas——

Mr. CHOPRA. I haven't looked——

Senator BEGICH.—or——

Mr. CHOPRA.—at that particular metric.

Senator BEGICH. Because, I mean, that's part of it. I mean, why people patent here—this is my assessment—is, we have some of the best patent laws. But, they don't manufacture, necessarily, al-

ways here, but they'll use the law to protect their patent when it's produced elsewhere.

So, is there such a study that shows us—or some——

Mr. CHOPRA. I will check.

Senator BEGICH.—data?

Mr. CHOPRA. I'm not familiar with the particular study. But, this cuts two ways, if I may, Senator. There are examples, in this increasingly global economy, where we want, and wish to encourage, U.S. innovation to solve global problems, often at price points that are dramatically lower than what the domestic U.S. market might otherwise seek.

I highlight, for example, an article written, in the Harvard Business Review, by Jeff Immelt, the CEO of GE. And forgive me for attempting to paraphrase his article; I may not do it in—its justice. But, his highlighting of the strategy, at GE, of reverse innovation—that is to say, they had engineered, for example, an electrocardiogram machine in rural China that, in order to be profitable, had to be 85 percent cheaper than the products that they would sell domestically in the U.S. This innovative company in the U.S. looked at that as a growth opportunity. They were successful in building a profitable product for the rural Chinese market, and not only did they generate sales and profitability overseas, they created innovations that, in the term that they used in the article, "reverse innovation" brought those ideas back to strengthen their innovation capacity in the domestic U.S. economy.

So, I'm not trying to suggest that your premise is a good one or a bad one; I'm just suggesting there's some nuance to the notion that an entrepreneurial company in the U.S. solving a global problem, at price points that are dramatically lower than what need here, could still see economic value bringing those innovations back and expanding.

So, I am—I will look into your question of the study, and I will see if there's a way to think through the implications of it.

Senator BEGICH. I'd appreciate it. And my time is up. But, the discussion I like to work off of is—show me the data that says—either way. Your description is a great example of a reverse. But, the other flip side is, What are we doing? And if people are developing here, in a sense of their idea—but then producing elsewhere, and then using our patent laws to protect what they produce elsewhere—we have to figure out the right balance here, because the reason is that we, the Federal Government, are allowing those opportunities of protection, but if we don't reap the benefit in some form—maybe it's the reverse, as you described, and/or the job creation—we have to figure out the right balance here.

Mr. CHOPRA. I will certainly——

Senator BEGICH. Now, that's the question.

Mr. CHOPRA.—look into that and get back to you, Senator.

Senator BEGICH. Great.

Mr. CHOPRA. Thank you for that.

Senator BEGICH. Thank you, Madam Chair.

Senator KLOBUCHAR. Well, thank you very much, Mr. Chopra. I hope you see that everyone is really raring to go here. We are impatient. We want to move forward. We know you get this. And we hope that we'll be working you a lot. I would really hope this would

become a major focus of the administration policy in the next year; and not just yours, but the entire administration.

So, thank you——

Mr. CHOPRA. My honor.

Senator KLOBUCHAR.—very much.

Mr. CHOPRA. Thank you for having me.

Senator KLOBUCHAR. All right, very good.

And now we're turning to our second panel. And we're going to be joined—I'll let them get up here, and we'll get them some new name tags, here.

We appreciate the interest in this hearing.

[Pause.]

Senator KLOBUCHAR. I see Mr. Chopra's fan club is leaving, and now we have our second——

[Laughter.]

Senator KLOBUCHAR.—panel.

All right. First of all, we have Andy Weiss. Mr. Andy Weiss is President and CEO of CoAxia, which I mentioned before, a small medical device business based out of Maple Grove, Minnesota. CoAxia develops innovative new treatments for stroke patients. He came to the company with 20 years of experience in the medical device industry, having worked for GE Medical, Vital Images, and Medtronic. He serves as an advisor to a number of small medical device business and venture capital firms, and is also the Director of Steady State Imaging, which is a company that develops advanced MRI medical imaging technologies.

We also have with us Dr. Robert Atkinson, who will be the first to testify here. He is the Founder and President of the Information Technology and Innovation Foundation, a nonpartisan think tank with the mission of promoting policies to advance technological innovation. He has an extensive background in technology policy, and has conducted groundbreaking research projects on technology and innovation.

Steve Ubl is President and Chief Executive Officer of the Advanced Medical Technology Association, the world's largest medical technology association. He previously ran his own healthcare consulting firm, and has served in other leadership roles with AdvaMed and the Federation of American Hospitals.

Rhys Williams, who Senator LeMieux already mentioned, is the President of New World Angels, Inc., an angel investment group in southeast Florida. He is also President of Tequesta BioVentures, and has co-founded several early-stage biotech companies. Prior to his current position, Mr. Williams worked as a venture capitalist, as an executive for a biotech company, and as an officer in the military, commanding an Army Special Forces combat diver detachment.

So, our witnesses come from diverse backgrounds, but all are focused on the same driving force, and that is innovation in America.

We will start with Dr. Atkinson.

STATEMENT OF DR. ROBERT D. ATKINSON, PRESIDENT, INFORMATION TECHNOLOGY AND INNOVATION FOUNDATION

Dr. ATKINSON. Great, thank you, Madam Chairwoman and Ranking Member LeMieux and Senator Begich. It's a pleasure to be here

on this critical issue of U.S. innovation and technological commercialization and competitiveness.

I think, as Senator LeMieux alluded to, the U.S. was in the lead for a long time, and, frankly, we're no longer in the lead in global innovation and competitiveness. There are other countries that have surpassed us, as we've documented in a report that was mentioned earlier.

There are a lot of reasons why I think we've lost our lead, but one of the key reasons is that a number of other nations have developed national innovation and competitiveness strategies, and, as part of those strategies, put in place comprehensive policies, everything from cutting corporate tax rates, creating generous incentives—tax incentives for R&D, to expanding government support for R&D. In contrast, the U.S. has really done very little in these areas.

In many ways—and, Senator LeMieux, you alluded to this—we're like that old commercial. The other countries are Avis. They're number two, and they try harder. And we're Hertz. We think we're number one, and we don't try harder. The reality is, we're not number one anymore, as I alluded to.

Ultimately, businesses are really going to have to drive this, but there are a lot of things the Federal Government can and should do to help play a more active role. And I allude to some of those in my testimony: certainly, skills and immigration policy; H–1B visas; increased funding for research, including Federal agencies, like the PTO and the FDA, both of which suffer from serious problems of review and backlog; a more generous R&E tax credit; and certainly more aggressive trade enforcement against what we would term "technology mercantilism," where other countries and systemically targeting U.S. technology leadership through unfair and oftentimes WTO-violating practices.

But, I want to just focus on two areas today, of how the Federal Government could play a better and more effective role. One is how we could reorganize some parts of the Federal Government to better spur innovation; and, second, how Federal policy could spur technology commercialization.

A first step—and, Senator Udall and Senator Warner alluded to this—would be for Congress to charge the administration with the creation of a national competitiveness and innovation strategy. We did this in the Recovery Act; we charged the FCC to create a broadband strategy. The FCC didn't simply just draft a memo; they actually brought in some of the leading thinkers and analysts in the country, from the private sector, and they worked diligently to create a very comprehensive and in-depth strategy, which I would argue is probably the best document we've produced in a long time in this area. We need to do the same thing in the area of competitiveness.

And I just mention, I really don't think this is about picking winners, or more government. When you look at what other countries have done with their strategies, they're really about smarter government, smarter regulation, smarter public investments, smarter tax policy. So, it's really looking at what the government's already doing, how we can do it better, what we can learn from our competitors.

Second, I think we could—and, by the way, I should add, all of my recommendations in the report, I'm—recognizing the fiscal constraint that we're under today, I'm trying to suggest a lot of recommendations, frankly, that really don't cost any money, or very little money, but would get a big bang for the buck.

I think one of those in that category would be for Congress to consider creating an Office of Innovation Review within OMB. In OMB, there's OIRA, and it's basically focused on cost benefit analysis. It really doesn't do anything about innovation. This goes to Senator Klobuchar's point. One of the things this group could do to essentially oversee what the FDA is doing, and make sure they're really doing the kind of job they need to do.

Second, we really need to push, much more, our science agencies—and, in particular, NSF—to focus and encourage them and incent them to drive industry/university partnerships. It's striking that the last time we faced a big challenge in competitiveness was in the 1980s. And one of the things we did, with strong bipartisan support from the Democratic Congress and the Reagan administration, was to really change a lot of the programs. We passed Bayh-Dole, obviously a bipartisan act, and we put in place a number of programs in the National Science Foundation to encourage universities and industries to work together to commercialize technologies, including the Engineering Research Center Program, the IUCRC program, and others.

I have to say, after two decades of looking at those programs, the evidence is unbelievably crystal clear. These programs are incredibly effective, they're largely underfunded. And NSF, basically, looks at them as second- tier programs that they ignore. The mission of NSF has basically morphed into one of supporting scientists at universities, with almost no attention to thinking about, how can we get those discoveries out to entrepreneurs to build businesses? And I think there's a lot the Federal Government could do. One of the things that we suggest is, in reauthorizing COMPETES or any other vehicles where there might be an increase at NSF or DOE Office of Science, is specifically allocate more money, to those programs that have been shown to work, that partner with industry.

Second, we could require NSF to—some of the programs that they have, they'd give money directly to universities—for example, some of the big equipment awards where they do that—to tie one of their criteria for getting an NSF award to how well the university actually works with industry. There is no accountability in the system right now. If you work with industry, you're graded the same as if you don't work with industry and entrepreneurs.

Third, we need to do a better job of providing support to universities and Federal laboratories for their technology transfer efforts. They're largely underfunded. We've proposed a very small levy on Federal research kind of like the SBIR, only much, much smaller—and using some of those funds to support that.

Finally, we should expand the regular R&E tax credit, but also, there's a provision in the R&E tax credit that was in the 1996 energy bill, on collaborative research and development tax credit, that gave companies a more generous tax credit to work with univer-

sities and Federal labs. But, it only applies to energy research. We think that word, "energy," should just be taken out.

I know I'm over my time. The last point I didn't put this in my written testimony, but I thought about it here today. As I think, Senator Klobuchar, you had mentioned, How do we get more financing to small business? I think one of the things we should consider is, How can we reform the SBIC program that SBA runs? It really has morphed into a program to fund later- stage large deals. That's not what the Federal Government should be doing. The Federal Government, to the extent it's in that space, should be helping venture firms go into earlier-stage smaller deals, and I think SBIC could be reformed in that direction.

Thank you very much.

[The prepared statement of Dr. Atkinson follows:]

PREPARED STATEMENT OF DR. ROBERT D. ATKINSON, PRESIDENT, INFORMATION TECHNOLOGY AND INNOVATION FOUNDATION

Madam Chair, Senator LeMieux, and members of the Committee, I appreciate the opportunity to appear before you to discuss the critical question of U.S. innovation and technology commercialization and what the Federal Government can do improve it.

I am the President of the Information Technology and Innovation Foundation. ITIF is a nonpartisan research and educational institute whose mission is to formulate and promote public policies to advance technological innovation and productivity. Recognizing the vital role of technology in ensuring American prosperity, ITIF focuses on innovation, productivity, and digital economy issues.

For over 50 years after WWII, the United States was the global innovation leader. However, in the last decade we have lost that lead and our rank appears to be rapidly slipping. The effects are seen in increased trade deficits, relatively lower increases in standards of living, higher unemployment, and even the severity of the current economic crisis.

While ultimately businesses and other organizations (*e.g.,* universities) will have to take the lead in driving innovation, the Federal Government can and should take a much more proactive role. There are two key kinds of activities the Federal Government can take to spur innovation.

First, we need to better organize the Federal Government to support innovation. A key first step would be for Congress to charge the administration with the creation of a national competitiveness and innovation strategy. In addition, Congress should consider creating an Office of Innovation Review within OMB to review all proposed Federal regulations for their impact on innovation. Finally, Congress should consider creating a new National Innovation Foundation that would house innovation-based programs now housed at agencies like NSF and NIST.

Second, it's time for Federal agencies, and particularly NSF, to focus much more on commercialization and industry partnerships. NSF is almost exclusively focused on providing funding for scientific research to universities and makes little effort to ensure that these results are commercialized and lead to jobs in the United States. Congress can play a key role in spurring more industry partnerships and commercialization at universities and Federal labs. First, as Congress increases science agency budgets, ITIF recommends that programs that focus specifically on industry partnerships and technology commercialization should receive a large share of the increases. Second, Congress should consider requiring NSF to tie funding to universities to the extent the latter work closely with industry and commercialize technology. Third, Congress should consider creating a new program to support university, state, and Federal laboratory technology commercialization initiatives, funded by a small "tax" levied on Federal research (the way SBIR and STTR are funded). Finally, we encourage Congress to expand R&D tax credit generally and also the scope of the current collaborative R&D credit.

We believe these steps would significantly increase technology innovation and related jobs in the United States. Moreover, these steps could be taken with almost no net negative budgetary impact.

What Is at Stake: Why Is Innovation Important?

In recent years, a growing number of economists have come to see that it is not so much the accumulation of more capital that is the key to improving standards of living; rather it is innovation—the creation and adoption of new products, services, processes, and business models.[1] When economists Klenow and Rodriguez-Clare decomposed the cross-country differences in income per-worker into shares that could be attributed to physical capital, human capital, and total factor productivity, they found that more than 90 percent of the variation in the growth of income per worker was a result of how effectively capital is used (*e.g.,* innovation).

Innovation is also essential if we are to create better jobs for all Americans. Properly conceived, innovation is not just about creating more jobs for engineers and managers in high technology industries. It is also about providing higher wage jobs for workers in manufacturing and "low-tech" services. Innovation also benefits not just the notable high-tech regions of the Nation, but all regions.

The growth of international trade also makes it increasingly important for the United States to innovate. Low-wage nations can now more easily perform labor-intensive, difficult-to-automate work. Indeed, it has become difficult for the United States to compete in such industries as textiles and commodity metals. Notwithstanding the efforts of countries like China and India to compete in advanced technology industries, for the foreseeable future their competitive advantage should remain in more labor-intensive, less complex portions of the production process.

By contrast, the United States' primary source of competitive advantage should be in innovation-based activities that are less cost-sensitive. To illustrate, a software company can easily move routine programming jobs to India where wages are a fraction of U.S. levels. There is less economic incentive for moving advanced programming and computer science jobs there because innovation and quality are more important than cost in influencing the location of these jobs.

The United States No Longer Leads the World in Innovation

The combination of its policy and non-policy strengths, combined with policy and non-policy weaknesses in other nations, enabled the United States to lead the world in innovation for the rest of the century after WWII. However, changes at home and abroad have meant that while the United States continues to have many strengths we no longer lead the world in innovation. We see signs of this relative decline in a wide array of indicators. The decline began at least in the 1980s, with the United States' shares of worldwide R&D investment, U.S. patents, scientific publications, researchers, and science and engineering degrees falling from the mid–1980s to the beginning of this century. But given our strong overall lead, the declines were not enough to dethrone us from our number one position.

Yet, since then the U.S. has continued to lag on a number of key factors, including growth in corporate and government R&D, scientific and technical degrees and workers, venture capital, and creation of new firms. As ITIF documented in its report *The Atlantic Century*, from 2000 to 2009, the United States slipped from number 1 to number 6 in global innovation-based competitiveness, falling behind nations such as Singapore, Denmark, Sweden, and South Korea on a per-GDP basis. The reason is that all of the other 39 nations or region examined made faster progress than we did on a collection of 16 innovation competitiveness indicators.

We also see the evidence of our decline in our trade performance. The trade deficit represents perhaps the most visible manifestation of the global challenge. At 5 percent of GDP in 2008, the current account deficit is at extremely high levels both in absolute terms and relative to the size of our economy.[2] The traditional U.S. trade surplus in agricultural products is nearing zero and in high-technology products has turned negative. In fact, the United States has actually run a negative trade balance in high-technology goods since October 1995. Meanwhile, our surplus in services trade is small and only holding relatively steady.

We also see it in the decline in U.S. manufacturing output as a share of GDP. This has been overlooked by many economists because the national economic accounts that track manufacturing output provide a misleading picture of the health of U.S. manufacturing by overstating output, particularly in the computer and semiconductors industry. According to the Department of Commerce's Bureau of Economic Analysis, manufacturing output as a share of GDP has stayed somewhat con-

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[1] Elhanan Helpman, *The Mystery of Economic Growth* (Cambridge, Massachusetts: Belknap Press, 2004).

[2] U.S. Bureau of Economic Analysis, "U.S. Current-Account Deficit Increases in 2006," News Release, March 14, 2007, *www.bea.gov/newsreleases/international/transactions/2007/pdf/transannual06_fax.pdf*.

stant between 1994 and 2008, at around 13.7 percent.[3] But drilling down to more detail causes a different, and more troubling picture to emerge. Over the last 25 years, the share of non-durable manufacturing output (*e.g.,* sectors such as chemicals, paper, and food products) declined from around 7 percent of GDP in 1993 percent to 4.7 percent in 2008. The share of durables (*e.g.,* sectors such as motor vehicles, wood products, and electronics), in contrast, increased to just over 9 percent in 2007, with a very slight decline in 2008, leading many to the rosy conclusion that while manufacturing employment may have declined, manufacturing output is still strong. But taking out computers and electronic products (NA ICS code 334) shows a very different picture, with durable goods output share declining from 7 percent in 1998 to 5.3 percent in 2008. Overall manufacturing output minus computers and electronic products declined from 13 percent of GDP in 1998 to just 9.7 percent in 2008.

Defenders of the status quo will respond that the proper measure is overall manufacturing, not manufacturing minus computers. But does anyone really think that the real inflation-adjusted value added of computers and electronic products really doubled between 2003 and 2007, which is what the BEA numbers suggest? The problem is that BEA counts output of computers based on improvements in Moore's law and when processing power doubles every 18 months or so it counts that in the value-added. It also appears to understate the value of imports in this sector, thus imputing more domestic output to the sector than is warranted. But this clearly overstates output and provides an extremely misleading picture of the real health of the U.S. manufacturing sector. For those who want to play down the threat to the U.S. manufacturing (and export) base, these statistics provide reassuring, if false, comfort. In 2011, the United States is poised to cede its title as the world's leading manufacturer—a position it has held for the last 110 years—to China.[4]

Factors Contributing to Our Relative Decline in Innovation-based Competitiveness

There are a number of factors which have contributed to the United States' relative decline in innovation-based competitiveness. Many point to globalization. With the emergence of globalization and relatively faster growth in income of many nations, one would expect to see the global share of U.S. output fall. And it is certainly true that as some advanced nations began to catch up (in part by emulating and going beyond our policies) the U.S. share of global innovation output (*e.g.,* R&D and patents) would also fall, although by less than overall economic output since the United States should actually be increasingly specializing in innovation-based activities as more routine-based production shifts offshore. But there was nothing preordained about the United States falling from number 1 in innovation competitiveness in 2000 to number 6 in 2009. The United States can and should remain the global innovation leader.

So what happened? As in explaining our success, non-policy and policy factors have played a role in our decline. There are a number of non-policy factors that appear to be at work. One key factor is the pressure from U.S. financial markets to prioritize increasing short-term returns to shareholders over growth or investments with longer-term payoffs, such as research and development and workforce training. Financial pressures have forced many U.S. firms to not only cut back on the growth of their research budgets, but to reallocate their research portfolios more toward product development efforts and away from longer term and more speculative basic and applied research. As Figure 1 shows, from 1991 to 2007, basic research as a share of corporate R&D conducted in the United States fell by 3.6 percentage points, while applied research fell by roughly the same amount, by 3.5 percentage points. In contrast, development's share increased by 7.1 percentage points. Moreover, corporate R&D as a share of GDP fell in the United States by 5 percent from 1999 to 2006, while in Europe and Japan it grew by 2 percent and 12 percent respectively. This has contributed to the U.S. share of global R&D falling from 39 percent in 1999 to 33 percent in 2007, while China's share increased fourfold.[5]

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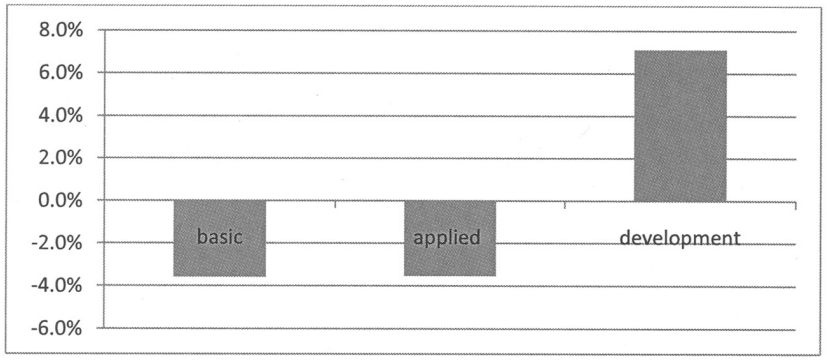
[3] U.S. Bureau of Economic Analysis, "Real Value-Added by Industry."

[4] Peter Marsh, "U.S. manufacturing crown slips," *Financial Times*, June 20, 2010, *http://www.ft.com/cms/s/0/af2219cc–7c86–11df–8b74–00144feabdc0.html*.

[5] Organization for Economic Co-operation and Development, "Ministerial Report on the OECD Innovation Strategy," May 2010, *www.oecd.org/dataoecd/51/28/45326349.pdf*.

Figure 1: Changes in the Shares of Corporate Basic and Applied Research and Development Between 1991 and 2007[6]



It's not just corporations that are investing relatively less on riskier R&D. So too are venture capital firms. Venture capital has been a vital, and, at least initially, a distinctively American component of our national innovation system. In 2008, venture capital-funded companies accounted for 11 percent of private sector employment and represented the equivalent of 21 percent of U.S. GDP.[7] But venture investments are moving downstream as VCs focus on the most attractive later stage deals. In fact, while total venture capital funding for zero and first stage deals increased from 1996–2008, the share of total venture capital going to zero and first stage deals actually declined from 35 to 24 percent in the same time period.[8] This equals a market failure around risk, leading to underinvestment in early stage start-up deals, and also resulting in a gap between the completion of basic research and applied R&D. In addition, more recently, the level of venture capital activity has declined considerably in the current recession. In the first quarter of 2009, total U.S. venture capital investment plunged 60 percent as compared to the same period a year earlier.

Another concern is that U.S. firms are moving R&D offshore. R&D expenditures from U.S.-based multinationals in emerging Asian markets increased from 5 percent to 14 percent between 1995 and 2006.[9] And over the last decade, the share of U.S. corporate R&D sites in the United States has declined from 59 percent to 52 percent, while the share in China and India increased from 8 to 18 percent.[10] Taken together, it is clear that the U.S. private sector engine of innovation is not working as well as it used to.

One reason for these private sector challenges is that U.S. policy has not kept up to provide the support and incentives needed for private sector innovation. Among 36 nations, the United States ranked just 21st in the growth of government investment in R&D from 1999 to 2006, with a growth rate of just 20 percent the average of the other nations. Since the mid-1990s, total Federal R&D investment grew at a sluggish 2.5 percent per year from 1994 to 2004—much lower than its long-term average of 3.5 percent growth per year from 1953 to 2004.[11] To restore Federal R&D support as a share of GDP to its 1993 level, we would have to increase Federal R&D investment by 50 percent, or over $37 billion.

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[6] Source: Authors' analysis of National Science Foundation data.

[7] Global Insight, "Venture Impact: The Economic Importance of Venture Capital-Backed Companies to the U.S. Economy," 2009, 2.

[8] While venture capital in the United States increased from $11.3 billion in 1996 to $28 billion in 2008, the amount invested in startup—and seed-stage deals only increased from $1.3 billion to $1.6 billion, or by one-third. The amount invested in early-stage deals rose from $2.8 billion to $5.3 billion between 1996 and 2008, but the early-stage share of total venture funding fell from about 25 percent to about 18 percent. Similarly the share of startup- and seed-stage venture capital fell from 11.6 to 5.8. Authors' analysis of 2008 data from PricewaterhouseCoopers/

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[9] "Science and Engineering Indicators: 2010," National Science Foundation, 2010, *http://www.nsf.gov/statistics/seind10/c0/c0s3.htm*.

[10] Booz Allen Hamilton and INSEAD, "Innovation: Is Global the Way Forward?" (Booz Allen Hamilton, 2006), 3.

[11] Titus Galama and James Hosek, *U.S. Competitiveness in Science and Technology* (Santa Monica, California: RAND Corporation, 2008), 67.

Indeed, the United States is one of only a few nations where total investment in R&D as a share of GDP actually fell from 1992–2005, largely because of that decline in public R&D support.[12] Among OECD countries, the United States now ranks seventh in total R&D intensity, behind a list of countries including Japan, South Korea, Finland, and Sweden.[13] Moreover, the United States places only 22nd in the share of government GDP devoted to non-defense research.[14]

Federal investment in most of the programs that focus most directly on innovation promotion have also declined or grown more slowly than GDP. Funding for NSF's Partnerships for Innovation program has grown more slowly than GDP since the program began operating in 2000. NIST's Manufacturing Extension Partnership (MEP) is scheduled to receive $131.8 million in FY10, only 3 percent more (not adjusted for inflation) than it did in 1999. The America COMPETES Act abolished ATP and created a new Technology Innovation Program (TIP) with a substantially broader scope than ATP. However, the legislation did not match the broader scope with increased funding. TIP is slated to receive $140.5 million in 2010, slightly more than ATP received in 2005 but less than ATP received in any year between 1998 and 2004. Funding for NSF's Engineering Education Center programs, which includes NSF's Engineering Research Centers (ERCs) have declined by 11 percent since 2004.[15]

The Defense Advanced Research Projects Agency (DARPA) has played a key role historically in driving innovation. The Internet grew out of a DARPA initiative. However, over the last decade, DARPA funding as a share of GDP has declined by over 20 percent. Moreover, in recent years DARPA has shifted toward more short term, mission-oriented development.[16] Indeed, it is not an exaggeration to state that if DARPA were making the kinds of investments it makes today 30 years ago, the Internet never would have been developed.

Lack of adequate funding has also severely impacted agencies like the Patent and Trademark Office (PTO) and the Food and Drug Administration that are critical to enabling inventions become innovations in the marketplace. Both the PTO and the FDA used to be the envy of other nations around the globe for their effectiveness and efficiency. But the backlog at the PTO means that most patent applicants will wait many years before finding out if their invention is granted a patent. Likewise, there have been increases in delays at the FDA for drug and device approval and difficulties in upgrading the scientific expertise the FDA needs in order to expeditiously and effectively evaluate new drugs and biological submissions.[17] Likewise, the United States Office of the Trade Representative lacks the resources it needs to adequately go after rampant high-technology mercantilist practices other nations are engaged in to take market share away from U.S. technology companies.

Finally, while our public and private research universities used to be the envy of the world, 20 years of underfunding by state governments have meant that many public research universities have fallen in capabilities relative to private research universities.[18] And while our research universities are still a key strength, their future is uncertain given the large cuts in state higher education budgets and slow growth in Federal support for university research.

The declines have not just been in direct spending. Relative to other nations our R&D tax credit has become significantly less generous. In the early 1990s, the United States had the most generous R&D tax credit among 30 OECD nations. Now, because other nations have expanded their R&D incentives, U.S. rank has fallen to 18th.[19] And among 38 nations, it ranks 24th, now behind India, Brazil, and China (India's R&D tax credit is now four times that of the United States). The reason for this slippage is that the United States ranks just 21st out of 24 OECD coun-

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[12] Organization for Economic Co-operation and Development, *OECD Science Technology and Industry Scoreboard 2005*, 2005.

[13] Organization for Economic Co-operation and Development, *OECD Science, Technology, and Industry Scoreboard 2007*, 2007, *http://oecd.p4.siteinternet.com/publications/doifiles/922007081PIG2.xls*.

[14] Norman Augustine, *Is America Falling Off the Flat Earth?* (Washington: National Academies Press, 2006), 53.

[15] FY 2005 and 2009 Budget Request to Congress, National Science Foundation.

[16] Erica Fuchs, "The Role of DARPA in Seeding and Encouraging New Technology Trajectories: Pre- and Post-Tony Tether in the New Innovation Ecosystem," *Industry Studies Working Paper*, (2009), *http://isapapers.pitt.edu/73/*.

[17] See Battelle Technology Partnership Practice, "Gone Tomorrow? A Call to Promote Medical Innovation, Create Jobs, and Find Cures in America" (Washington, D.C.: The Council for American Medical Innovation, June, 2010).

[18] James Adams, "Is The U.S. Losing Its Preeminence in Higher Education?" *NBER Working Paper* 15233, (2009).

[19] Organization for Economic Co-operation and Development , *OECD Science, Technology, and Industry Scoreboard 2009*, 79, *http://dx.doi.org/10.1787/744214584778*.

tries assessed in rate of change in tax credit generosity between 1999 and 2008. Congress would need to increase the Alternative Simplified Credit (ASC) from 14 to 20 percent to reach 10th place and 47 percent to become the most generous of the OECD nations.[20]

Weaknesses in the U.S. innovation system don't simply stem from underfunding. The organization of efforts is often not optimal to driving innovation. Perhaps the most striking weakness is the fact that although there are a number of programs that help companies become more innovative or productive, there is no agency that has firm-level innovation as its sole mission. (In stark contrast to the litany of nations listed below who do have such an agency.) With a few important exceptions, U.S. innovation policy is at best a byproduct of Federal programs whose main purpose lies elsewhere.

In addition, as the U.S. innovation system has spread out to all states and corners of the nation, the Federal system has remained national in scope. Washington is often far removed from the firms and other institutions that drive innovation. This is particularly true for small and mid-sized firms. In contrast, state and local governments and metropolitan-level economic developers have a long track record of creating organizations that work more closely with firms. Unfortunately, most existing Federal programs do not work through or in collaboration with state or local governments or regional organizations, which are often more flexible and less remote from production processes.[21] Federal program managers and policymakers all too often seem to assume that there is one uniform national economy in which regional agglomerations are at best a sideshow.

What Can We Learn from Other Nations?

Over the last 15 years, a large number of nations have woken up to the fact that they need to compete for internationally mobile innovation-based economic activities, and have put in place policies that reflect that determination, such as more generous R&D tax incentives and stronger government support for all stages of research. In contrast, the United States has lagged behind, believing that it needed to do little since it had long been the global innovation leader. As a result, U.S. firms are now competing against firms in a growing number of national economies in which their governments actively help them compete.

Many forward-thinking countries have made innovation-led economic development a centerpiece of their national economic strategies during the past decade. These nations know that moving up the value chain to more innovation-based economic activity is a key to boosting productivity, and that losing the competition can result in a relatively lower standard of living as economic resources shift to lower-valueadded industries. These countries are implementing coordinated national innovation agendas that boost R&D funding, have introduced policy changes and government initiatives that more effectively transfer technologies from universities and government laboratories to the private sector for commercialization, and are ensuring that immigration policies support innovation. While many nations have taken the innovation challenge to heart and put in place a host of policies to spur innovation, the United States has done little, consequently falling behind in innovation policies and in innovation performance as well.

These innovation-support policies are crucial to national innovation competitiveness, as Professors Furman and Richard found in a study of the innovation capacity (an economy's potential for producing a stream of commercially relevant innovations) of twenty-three countries from 1978 to 1999.[22] Starting with 1978, they classify countries as either world-leading innovators (the United States, Germany, Japan), middle-tier (Great Britain, France, Australia), third-tier (Spain, Italy), or "emerging" innovators (Ireland, Taiwan) based on countries' patenting activity per capita, a proxy for commercialized innovations.

A number of these "emerging innovators"—among them Ireland, Finland, Singapore, South Korea, Denmark, and Taiwan, in particular—achieved remarkable increases in innovative output per capita, moving to the world's technological frontier and overtaking the innovative capacities of many mid- and third-tier countries, including France and Italy, whose economic conditions started off much more favorably in the early 1980s. Furman and Hayes conclude that the innovation leadership these countries achieved was based not only on the development of innovation-en-

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[20] Robert Atkinson and Scott Andes, "U.S. Continues to Tread Water in Global R&D Tax Incentives," Information Technology and Innovation Foundation, 2009, *http://www.itif.org/files/WM-2009-03-rd.pdf*.

[21] Issues of the State Science and Technology Institute's *Weekly Digest* provides examples (*www.ssti.org*).

[22] Jeffrey L. Furman and Richard Hayes, "Catching up or standing still? National innovative productivity among "follower" countries, 1978–1999," *Research Policy* 33 (2004): 1329–1354.

hancing policies and infrastructure, such as strong IP protections, openness to trade, highly competitive markets, and strong industry clusters, but also a commitment to maintaining substantial financial and human capital investments in innovation.

1. National Innovation Strategies

Part of the United States' leadership slippage is attributable to the fact that over the past decade many of our competitors—from Great Britain and Finland to Japan and South Korea—have created national innovation and competitiveness strategies designed specifically to link science, technology, and innovation with economic growth.[23] As Annabelle Malins, British Consul General for the Southern U.S., commented recently, "The United Kingdom has made a conscientious decision to place innovation at the center of our country's economic growth strategy."[24] Where these countries have coherent, strategic game plans to compete and win in the highest value-added sectors of economic activity, the U.S. relies more on one-off policies that, while valuable and necessary, are all too often not tied to a coordinated strategy.

These nations are not content to let their government policies and actions influence innovation in a haphazard and uncoordinated way. They seek to develop strategies to assess their nation's weaknesses and strengths, examine the policies of other nations in order to learn from them, and assess and revise their own national policies in a broad array of areas that could influence innovation and competitiveness, including tax policy, regulation, direct science and technology programs and other areas (see Table 1).

It should be noted that these strategies seldom seek to "pick winners and losers" in the sense of picking individual firms to favor. Indeed, these strategies are a far cry from the strongly directive Japanese efforts, for example, of the 1980s. They do not try to decide the path of business innovation and then induce firms to follow that path. Instead, they exemplify the cooperative, facilitative government role that is needed to address the market failures that hamper the innovation process. And they seek to better align what government already does to ensure that it best supports innovation and competitiveness.

Table 1.—Selected Countries with a National Innovation Strategy and/or Foundation

Country	National Innovation Strategy	National Innovation Agency
Australia	Yes	Yes
Austria	Yes	Yes
Canada	Yes	No
China	Yes	No
Denmark	Yes	Yes
Finland	Yes	Yes
France	Yes	Yes
Germany	Yes	No (Yes at the Bundeslander level)
India	Yes	Yes
Ireland	Yes	Yes
Japan	Yes	Yes
Malaysia	Yes	Yes
The Netherlands	Yes	Yes
Portugal	Yes	Yes
Norway	Yes	Yes
Rwanda	Yes	No
Singapore	Yes	Yes
South Korea	Yes	Yes
Spain	Yes	Yes
Sweden	Yes	Yes
Thailand	Yes	Yes
United Kingdom	Yes	Yes
United States	Yes	No
Uruguay	Yes	Yes

2. Civilian Technology and Innovation Promotion Agencies

Many countries not only have innovation and competitiveness strategies, but also agencies specifically charged with spurring private sector innovation. In recent years, Finland, France, Iceland, Ireland, Australia, Japan, the Netherlands, New Zealand, Norway, South Korea, Canada, Germany, Taiwan, Switzerland and Great

[23] Stephen Ezell, "America and the World: We're Number 40!," *Democracy Journal*, Issue 14, Fall 2009, *http://www.democracyjournal.org/pdf/14/Ezell.pdf*.

[24] Annabelle Malins, "Address to National Foreign Trade Council," Raleigh, North Carolina, April 15, 2010.

Britain have all either established or significantly expanded separate innovation promotion agencies (see Table 1). Many countries have launched such agencies only fairly recently. For example, India launched its National Innovation Foundation in 2000, Sweden introduced Vinnova in 2001, Thailand created a National Innovation Agency in 2003, the launched Senter November in 2004, and the United Kingdom launched its Department for Business, Innovation, and Skills in 2009.

All these countries have science- and university-support agencies similar to America's National Science Foundation, which largely fund basic research. But these countries realized that if they were to prosper in the highly competitive, technology-driven global economy, they needed specifically to promote technological innovation, particularly in small and mid-sized companies and in partnership with universities.

These countries' innovation agencies perform roles such as channeling R&D into specific technology or industry research areas; surveying the world to identify nascent technologies; building technology "roadmaps"; creating new knowledge pertaining to the methods, processes, and techniques of innovation; transferring knowledge from academia and government to the private sector; encouraging private-sector technology adoption; catalyzing industry-university research partnerships; supporting regional industry "technology clusters"; developing national innovation metrics; and championing innovation in the public sector.

Perhaps the most ambitious of these efforts is Tekes, Finland's National Agency for Technology and Innovation. In the last two decades, Finland has transformed itself from a largely natural resource-dependent economy to a world leader in technology, with Tekes a key player in the country's transformation. Affiliated with the Ministry of Employment and the Economy, Tekes funds many research projects in companies, multi-company partnerships, and business-university partnerships. With a budget of $560 million (in a country of only 5.2 million people), Tekes works in partnership with business and academia to identify key technology and application areas—including nano-sensors, ICT and broadband, health care, energy and the environment, services innovation, and manufacturing and minerals—that can drive the Finnish economy. Tekes also operates a number of overseas technology liaison offices that conduct "technology scanning," seeking out emerging technologies bearing on the competitiveness of Finnish industries, and sponsors foreign outreach efforts to help its domestic companies partner with foreign businesses and researchers.

One of the benefits of these programs is that they not only fund research projects but also facilitate networking and collaboration. For example, Tekes brings together in forums many of the key stakeholders in the research community. For each of its 22 technology areas there are networking groups of researchers. In addition, Tekes publishes a description of each project it funds. Through these processes, researchers learn more about research areas and gain opportunities to collaborate. Many agencies also work with industry on "roadmapping" exercises, whereby key participants (industry and academic researchers and government experts) identify technology challenges and key areas of need over the next decade. They then base their selection of research topic funding on the results of the roadmap exercise. The UK's Technology Strategy Board is funding over 600 collaborative business-university research projects which have been launched over the past two to 3 years. Like Tekes, it is also responsible for more than 20 industry- and technology-based knowledge transfer networks, with more being established.

In virtually all cases these nations have made an explicit decision not to place their innovation-promotion initiatives under the direct control of large government departments. Although most innovation-promotion agencies are affiliated with those departments, they usually have a substantial degree of independence. It is common for these agencies to have their own executive director and a governing board of representatives from industry, government, university, or other constituency groups. For example, Japan's government recently made a conscious choice to establish NEDO as an autonomous agency because it realized that MITI, as a large government bureaucracy, did not have the flexibility needed to manage such a program. NEDO is governed by a board of directors, with the Chair appointed by MITI and members from industry, universities, and other government agencies.

These nations also often invest considerable resources in these efforts. If the United States wanted to match Finland's outlays per dollar of GDP in innovation-promotion efforts, it would have to invest $34 billion per year. In fact, it invests around $3 billion per year, or 0.02 percent of GDP. While other nations invest less in their innovation-promotion agencies than Finland, they still invest considerably more than the United States. As a percent of their countries' GDPs, Sweden spends 0.07 percent, Japan 0.04 percent, and South Korea 0.03 percent on their innovation promotion agencies. To match these nations on a per-capita basis, the United Sates would have to invest $9 billion to match Sweden, $5.4 billion to match Japan, and

$3.6 billion to match South Korea.[25] It is astounding that economies a fraction the size of the United States spend more on innovation promotion in *actual dollars*, let alone as a percentage of their economy.

This places U.S. industries and corporations operating alone at a disadvantage against foreign corporations that benefit from coordinated and enlightened national strategies among universities, governments, and industry collaborations to foster competitiveness. For example, the Japanese government has recognized advanced battery technology as a key driving force behind its competitiveness, and views battery technology as an issue of "national survival."[26] It is funding Lithium-ion battery research over the five-year period from October 2007 to October 2012 at $275 million (¥25 billion), and longer term has committed to a 20-year Li-ion battery research program. Germany's government will provide a total of €1.1 billion ($1.4 billion) over 10 years to applied research on automotive electronics, lithium ion batteries, lightweight construction, and other automotive applications.[27]

3. Tax Incentives for Research and Development

As noted above, many other nations have much more generous tax incentives for the private sector to invest in R&D. They do this not only to encourage existing companies to expand R&D, but to attract globally mobile R&D activity. But not only have these nations put in place more generous research incentives they have been more innovative in using incentives to spur research and innovation. For example, some countries, including Denmark and the Netherlands, have begun to extend R&D tax credits to cover process R&D activities, effectively extending the R&D tax credit from their goods to services industries as well. Other nations have more generous credits for companies investing in national laboratories or universities. For example, in France, companies funding research at national laboratories receive a 60 percent credit on every dollar invested. Denmark, Hungary, Norway, Spain, and the U.K. provide firms more generous tax incentives for collaborative R&D with public research institutions. Japan's R&D incentive for research expenditures companies make with universities and other research institutes is almost twice as generous as its regular credit.

Other nations are increasingly providing tax incentives to treat income received from patents more generously. For example, Belgium taxes income received from patents at a rate of 0 to 6.8 percent and Ireland at 0 percent. Switzerland has reduced corporate taxes on income from all intellectual property to between 1 and 3 percent. Just this year, the Netherlands expanded this incentive to include income derived from patents or R&D which are taxed at just 5 percent.[28]

Steps Congress Can Take to Boost U.S. Innovation and Competitiveness

The government's role in addressing the innovation economy is not to regulate business or to direct the path of technological development. We do not advocate a heavy-handed, government-driven industrial policy. Indeed, such a policy cannot be nimble enough to respond to the kinds of market failures that afflict the innovation process.

At the same time, though, we do not advocate simply "leaving it up the market" not only because the innovation economy is rife with market failures but also because U.S. firms are now in global competition with firms that have their government as an innovation partner. In this sense, government should be a facilitator that spurs firms to innovate in ways that serve the public interest. In short, while we believe that the private sector should lead in innovation, we also believe that in an era of globalized innovation and intensely competitive markets the Federal Government can and should play an important enabling role in supporting private sector innovation efforts.

As a core of this strategy, the Federal Government needs to invest significantly more in scientific research, commercialization, and innovation, including funding entities like the PTO and FDA that help support the innovation process. ITIF rejects the notion that in a time of fiscal constraint innovation investments should take

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[25] Expenditures for Finland, Sweden, Japan, and South Korea are based on personal correspondence between the authors and representatives of the respective nations' innovation-promotion agencies. Inference for the United States is from the authors' analysis.

[26] Testimony of Don Hillebrand, Ph.D., Director, Center of National Transportation Research at Argonne National Laboratory, to House Appropriations Subcommittee on Energy and Water Development, February 14, 2008.

[27] *Auto Industry U.K.*, "Germany invests €420M in lithium-ion battery development," May 13, 2008, *http://www.autoindustry.co.uk/news/13–05–08_2*.

[28] The Netherlands Ministry of Finance, "Doing business in the Netherlands," *http://www.minfin.nl/english/Subjects/Taxation/Doing_business_in_the_Netherlands/Innovation_box*.

their share of cuts, just like all other budget items. The reality is that investments in innovation are not like all other areas of the budget, most of which produce no or little additional economic activity and tax revenues. If structured properly Federal investments in innovation (either through direct spending or tax incentives), can more than pay for themselves, not only in terms of jobs and economic growth, but also tax revenues.

However, given the current political climate that favors cutting the deficit over investing in America's future, I will focus my recommendations on activities that will have limited budgetary impact. If policies are crafted carefully, achieving greater levels of innovation and commercialization of R&D while recognizing budget limitations need not be mutually exclusive. Even in a time of budget constraints there are many pro-innovation policies Congress can pursue that will add little to the Federal deficit (under its current static and short-term budgetary scoring system).

With this in mind, I offer the following set of innovation-enhancing policy proposals, each designed to be of low or no cost to the Treasury, but whose impact on enhancing U.S. innovation and competitiveness could be significant. These are organized into two areas: (1) changes in the structure of the Federal Government to better support innovation and (2) enacting policies to spur university-industry partnerships and technology commercialization.

Before going into detail on these, let me make it clear that we believe that there are a wide range of policies that can spur innovation and should be the focus on national innovation policy. Three in particular are worth mentioning here. First, high-skill immigration reform to make it easier for the U.S. to attract and retain the best and the brightest from around the world is a key step Congress could take. As we recently noted, the old arguments that these highly-skilled immigrants take jobs away from Americans or lower their wages are simply not true.[29] Second, Congress and the Administration need to do more to fight foreign "high-tech" mercantilism. As ITIF has shown, many nations are using an array of unfair trade practices, including standards; government procurement; anti-trust; intellectual property theft, including product counterfeiting; and other policies to systematically disadvantage U.S. technology companies in the global marketplace. U.S. trade policy needs to more aggressively go after these violations of the spirit and often the letter of the WTO.[30] Third, we need to expand our tax incentives for R&D. ITIF recently calculated that expanding the Alternative Simplified Credit from 14 percent to 20 percent would after several years created 162,000 jobs and actually lead to a net increase in Federal tax revenues of $9 billion annually.

I. Restructure the Federal Government to Better Support Innovation

The Federal Government plays a key role in innovation. To be most effective, Federal policy should be aligned wherever possible to proactively support innovation. President Obama took an important step in this direction with the creation of the position of a Chief Technology Officer in the White House. But more needs to be done. ITIF suggests three key changes:

1. *Create a National Innovation and Competitiveness Strategy Modeled on the National Broadband Strategy.* The United States needs to create millions of new good-paying jobs over the next decade. If the United States wants to do this and be successful in the global economy, it is critical that the Federal Government develop a serious, in-depth, and analytically-based national competitiveness strategy. As noted above, we are one of the few nations without one. The last time the United States did anything similar was President Carter's Domestic Policy Review on Industrial Innovation in 1978 and President Reagan's 1984 Commission on Industrial Competitiveness. These efforts were extremely important in setting the stage for a number of important Congressional initiatives, including the R&D tax credit, the Bayh-Dole Act, the National Cooperative R&D Act, the Stevenson-Wydler Technology Innovation Act, and the Omnibus Trade and Competitiveness Act.

The American Recovery and Reinvestment Act charged the FCC with the development of a national broadband plan. The next America COMPETES Act should charge the Administration with the development of a national competitiveness strategy. Adequate funding should be provided to bring in an outside director with deep

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[29] New academic research has found that H1–B visa workers do not take jobs away from American workers, nor do they reduce their wages. Cited in Robert D. Atkinson, "H–1B Visa Workers: Lower-Wage Substitute, or Higher-Wage Complement, (Washington, D.C.: ITIF, June, 2010), *http://www.itif.org/publications/h-1b-visa-workers-lowerwage-substitute-or-higher-wage-complement*.

[30] Julie Hedlund and Robert Atkinson, "The Rise of the New Mercantilists: Unfair Trade Practices in the Innovation Economy, (Washington, D.C.: ITIF, June 2007), *http://www.itif.org/issues/15?page=2*.

technical and policy knowledge and hire individuals with technical and business experience.

A national innovation strategy would provide an opportunity to engage in a comprehensive analysis of the key factors contributing to future U.S. competitiveness. Legislation could require that the strategy focus on a number of broad issues, going more in depth on each. These should include assessing: (1) current U.S. competitiveness, including at the major industry level; (2) current business climate for competitiveness (including tax and regulatory); (3) trade and trade policy issues; (4) education and training; (5) science and technology policy; (6) regional issues in competitiveness (including the role of state and local government and impacts on rural, urban and other regions); (7) measurement and data issues; and (8) proper organization of government to support a comprehensive innovation and competitiveness agenda.

2. *Form an Office of Innovation Review in OMB (i.e., an Office of Information and Regulatory Affairs for Innovation).* The relative absence of innovation from the agenda of many relevant Federal agencies—as well as interagency processes such as the centralized cost-benefit review performed by the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB)—manifests the confluence of two regulatory challenges: first, the tendency of political actors to focus on short-term goals and consequences; and second, political actors' reluctance to threaten powerful incumbent actors. Courts, meanwhile, lack sufficient expertise and the ability to conduct the type of forward-looking policy planning that should be a hallmark of innovation policy.

To remedy these problems, we recommend that Congress create a White House Office of Innovation Review that would have the specific mission of being the "innovation champion" within these processes. OIR would be an entity that would be independent of existing Federal agencies and that would have more than mere hortatory influence. It would have some authority to push agencies to act in a manner that either affirmatively promoted innovation or achieved a particular regulatory objective in a manner least damaging to innovation. OIR would operate efficiently by drawing upon, and feeding into, existing interagency processes within OIRA and other relevant White House offices (*e.g.,* the Office of Science and Technology Policy). It is important to note that OIR would not be designed to thwart Federal regulation; as a matter of fact, in some cases, the existence of OIR might lead to increased Federal regulation (*e.g.,* more Environmental Protection Agency regulations might pass muster under cost-benefit analysis if innovation-related effects were calculated).

Some might question the significance of this proposal. Isn't creating OIR a fairly small change to the system? Certainly adding OIR to the existing mix is a smaller change than jettisoning the existing substantive agencies in favor of a new agency with authority to regulate, and promote, innovation across all government agencies. But implementing this proposal will significantly change the regulatory environment. First, an entity focused on innovation would add an important new voice to the regulatory conversation. There would now be an entity speaking clearly and forthrightly on the centrality of innovation. Second, and more important, OIR would not merely have a voice: it would be able to remand agency actions that harm innovation. It would also have as part of its mission proposing regulation that benefits innovation. This is no small matter. Indeed, it would change the regulatory playing field overnight.

3. *Establish a National Innovation Foundation.* If Congress wanted to more effectively organize Federal innovation implementation efforts, it could establish a National Innovation Foundation (NIF)—a new, nimble, lean, and collaborative entity devoted to supporting firms and other organizations in their innovative activities.[31] A National Innovation Foundation would:

- Catalyze industry-university research partnerships through national sector research grants.
- Expand regional innovation-promotion through state-level grants to fund activities like technology commercialization and entrepreneurial support.
- Encourage technology adoption by assisting small and mid-sized firms in taking on existing processes and organizational forms that they do not currently use.
- Support regional industry clusters with grants for cluster development.

[31] Robert Atkinson and Howard Wial, "Boosting Productivity, Innovation, and Growth Through a National Innovation Foundation," (Washington, D.C.: Information Technology and Innovation Foundation and The Brookings Institution, April 2008), *www.itif.org/publications/boosting-productivity-innovation-and-growth-through-national-innovation-foundation.*

- Emphasize performance and accountability by measuring and researching innovation, productivity, and the value-added to firms from NIF assistance.
- Champion innovation to promote innovation policy within the Federal Government and serve as an expert resource on innovation to other agencies.

By doing these things, NIF would address quite robustly each of the major flaws that weaken Federal innovation policy. Creating NIF could be done in a budget neutral way by consolidating existing programs (with around $350 million in annual support). Because of its strong leveraging requirements from the private sector and state governments, NIF would lead to an expansion of overall national efforts devoted to innovation.

II. Spur University Industry Partnerships and Commercialization

As companies have reduced their relative investment in basic and applied research, universities and Federal laboratories have become more important to the U.S. innovation system. As Fred Bloch and Matthew Keller documented in a recent ITIF report, *Where Do Innovations Come From? Transformations in the U.S. National Innovation System, 1970–2006*, in 2006 76 of the 88 companies that produced award-winning innovations were beneficiaries of Federal funding.[32] Today, the private sector increasingly relies upon partners in universities and Federal laboratories when developing innovations. Indeed, universities are becoming more important players in the innovation process.

However, the current Federal system for funding research pays too little attention to the commercialization of technology, and is still based on the linear model of research that assumes that basic research gets easily translated into commercial activity. In fact, the process is ripe with barriers, including institutional inertia, coordination and communication challenges, and lack of funding for proof of concept research and other "Valley of Death" activities.

Not surprisingly, many universities and Federal labs underperform when it comes to working with industry and commercializing technologies. The major reason for this is that few universities and Federal labs see commercialization and industry partnerships as a central part of their mission. In this context, the Federal Government can and should take a number of steps to support and incent universities and labs to more effectively commercialize technology. They can do this in a variety of ways.

4. *Focus Increases in Science Agency Budgets on Programs That Focus on Commercialization*. The National Science Foundation is fundamentally an agency which focuses on supporting university-based science, not on the transfer of these results to the marketplace. And this is reflected in part in the minimal levels of funding for NSF programs that seek to create partnerships with industry, such as the Engineering Research Center Program and other related programs. These partnership programs receive less than 2 percent of the overall NSF budget.[33] Unless Congress specifically charges the NSF with focusing more on commercialization and significantly increases funds for the programs that have that as their mission, the NSF will continue to give these programs short shrift.

As such, we recommend that Congress not just simply expand science agency funding across the board within NSF, NIST, and DOE Office of Science (as is contemplated in the reauthorization of the COMPETES Act), but that Congress target a significant share of increased funding to the programs more focused on commercialization activities. In particular, COMPETES reauthorization should look to increase by a factor of four (over a period of 3 years) funding for NSF's Engineering Research Center program, the Industry/University Cooperative Research Centers (I/UCRC), Partnerships for Innovation, Grant Opportunities for Academic Liaison with Industry, and Advanced Technical Education (ATE) Program. These programs not only effectively leverage non-Federal dollars (for example, I/UCRCs leverage 10 to 15 times the NSF investment), they effectively link universities and colleges to industry.

Some will object to such targeting, arguing that the funds should go to "basic" university research. But there is no reason why some share of university research cannot be oriented toward problems and technical areas that are more likely to have economic or social payoffs to the Nation. Science analyst Donald Stokes has described three kinds of research: purely basic research (work inspired by the quest

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[32] Fred Bloch and Matthew Keller, "Where Do Innovations Come From? Transformations in the U.S. National Innovation System, 1970–2006," Information Technology and Innovation Foundation, July 2008, *http://www.itif.org/files/Where_do_innovations_come_from.pdf*.

[33] FY 2009 Budget Request to Congress, National Science Foundation, *http://www.nsf.gov/about/budget/fy2009/toc.jsp*.

for understanding, not by potential use), purely applied (work motivated only by potential use), and strategic research (research that is inspired both by potential use and fundamental understanding).[34] One way to improve the link between economic goals and scientific research is to fund more strategic research in partnership with industry and universities.

5. *Tie Federal Research Awards to University Commercialization Results.* Currently, NSF awards grants to universities solely on technical merit, not on whether the university is effective on transferring the results of that research into society and the economy. ITIF recommends that America COMPETES legislation include incentives for accountability. The legislation contemplates more dollars and more grants for private investigator scientific research; but we need greater accountability for results—a challenge we've had for more than 20 years. Many countries are experimenting with measures that would bring greater accountability to show results from government-funded scientific research. For example, in Sweden, 10 percent of regular research funds allocated by the national government to universities are distributed using performance indicators. Five percent of these funds are allocated based on the amount of external funding the institutions have been able to attract, with the other 5 percent based on the quality of scientific articles published by each institution (as determined through bibliometric measures such as the number of citations).[35] Finland has also started to base its university budgets on performance—25 percent of Finnish universities' research and research training budgets are based on "quality and efficacy" including the quality of scientific and international publications and the universities' ability to attract research investment from industry.[36]

One way to begin this process would be for Congress to charge NSF with using the criteria of the share of the university's research budget that is provided by industry when it makes awards to institutions (as opposed to individual scientists). Programs using this criteria might include the NSF Major Research Equipment and Facilities Construction Funding program, the Major Research Instrumentation program, and the Technology and Tools Funding program. If universities understand that their likelihood of receiving NSF grants is increased if they work more closely with industry, they will likely do so.

6. *Create an SCNR (Spurring Commercialization of Our Nation's Research) Program to Support University, State, and Federal Laboratory Technology Commercialization Initiatives.* In addition to using Federal research funding as an incentive for universities to work more with industry, ITIF believes that the Federal Government should also provide funding to directly support commercialization activities. However, in an era of fiscal constraint adequate new funding may be difficult to obtain. As a result, Congress should consider establishing an automatic set-aside program taking a modest percentage of Federal research budgets and allocating them to a technology commercialization fund. Currently the SBIR program allocates 2.5 percent of agency research budgets to small business research projects; the STTR program allocates 0.3 percent to universities or nonprofit research institutions that work in partnership with small businesses. If Congress allocated 0.15 percent of agency research budgets it would raise around $110 million per year to fund university, Federal laboratory, and state government technology commercialization and innovation efforts. (The 0.15 percent share could either be added on top of the existing 2.8 percent allocation currently going to SBIR and STTR, or it could be taken from the SBIR share.)

This program would be different than the STTR program which funds small businesses working with universities.[37] We would recommend that half the funds would go to universities and Federal laboratories that could use the funds to create a variety of different initiatives, including mentoring programs for researcher entrepreneurs, student entrepreneurship clubs and entrepreneurship curriculum, industry outreach programs, seed grants for researchers to develop commercialization plans, etc. The other half of funds would go to match state technology-based economic development (TBED) programs. Since the 1980s, when the United States first began to face global competitiveness challenges, all 50 states have established TBED programs. Republican and Democratic Governors and legislators support these programs because they recognize that businesses will not always create

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[34] Donald Stokes, "Pasteur's Quadrant," Brookings Institution, 1997.

[35] Swedish Ministry of Education and Research, "Government Bill: A Boost to Research and Innovation," November 17, 2008, *http://www.sweden.gov.se/sb/d/6949/a/115809*.

[36] Jukka Haapamäki and Ulla Mäkeläinen, "University Steering," Finnish Ministry of Education, June 17, 2009.

[37] U.S. Small Business Administration, "Description of the Small Business Technology Transfer Program," 15. *http://www.sba.gov/aboutsba/sbaprograms/sbir/sbirstir/SBIR__STTR__DESCRIPTION.html*.

enough high-productivity jobs in their states without government support. State and local governments now invest about $1.9 billion per year in TBED activities, a fraction of what they spend on industrial recruitment to convince firms to move from one state to another. States are a key partner in the U.S. innovation system, and the Federal Government needs to better support their technology commercialization efforts.

7. *Expand the Scope of the Collaborative R&D Tax Credit.* Increasingly, firms are collaborating with other firms or institutions in order to lower the cost of research and increase its effectiveness by maximizing idea flow and creativity. Indeed, a growing share of research is now conducted not only on the basis of strategic alliances and partnerships but also through ongoing networks of learning and innovation. Moreover, participation in research consortia has a positive impact on firms' own R&D expenditures and research productivity.[38] And OECD analysis shows that firms that collaborate on innovation spend more on innovation than those that do not, an indication that collaboration is more a means to extend the scope of a project or complement firms' competencies than simply a means to save on costs.[39]

Yet, most collaborative research, whether in partnership with a university, national laboratory, or industry consortium, is more basic and exploratory than research typically conducted by a single company. Moreover, the research results are usually shared, often through scientific publications. As a result, firms are less able to capture the benefits of collaborative research, leading them to under-invest in such research relative to socially optimal levels.[40] This risk of underinvestment is particularly true as the economy has become more competitive, and a reflection of this is the fact that for the first time since the data were collected in 1953, the percentage of U.S. academic R&D supported by industry declined over a 6-year period, from 2000 to 2006 (before experiencing a modest increase in 2007).[41] This may stem from the fact that university contracts are often undertaken as discretionary activities and are the first to be cut when revenues are down.[42]

ITIF urges Congress to provide a more generous incentive for collaborative research. As part of the Energy Policy Act of 2005, Congress created an energy research credit that allowed companies to claim a credit equal to 20 percent of the payments to qualified research consortia (consisting of five or more firms, universities, and Federal laboratories) for energy research. To spur more collaborative research, Congress could allow firms to take a flat credit of 20 percent for all collaborative research conducted at universities, Federal laboratories, and research consortia, not just that related to energy.

Conclusion

For over half a century, the United States led the world in innovation on a per-GDP and per-capita basis. This leadership role not only enabled America to be the leading military power, it enabled us to be the leading economic power, with the resultant economic and social benefits that came with that. But now more than ever, the American standard of living depends on innovation. To be sure, companies are the engines of innovation and the United States has an outstanding market environment to fuel those engines. Yet firms and markets do not operate in a vacuum. By themselves they do not produce the level of innovation and productivity that a perfectly functioning market would. Even indirect public support of innovation in the form of basic research funding, R&D tax credits, and a strong patenting system, important as they are, are not enough to remedy the market failures from which the American innovation process suffers.

At a time when America's historic lead in innovation has evaporated and its relative innovation competitiveness continues to shrink, when more and more high-productivity industries are in play globally, and when other nations are using explicit public policies to foster innovation, the United States cannot afford to remain complacent. Relying solely on firms acting on their own will increasingly cause the United States to lose out in the global competition for high-value added technology and knowledge-intensive production. Congress has an opportunity to take steps now to stop and reverse this slide.

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[38] L. Branstetter and M. Sakakibara, "Japanese Research Consortia: A Microeconometric Analysis of Industrial Policy," 21, *Journal of Industrial Economics*, 46 (1998): 207–233.

[39] OECD, "Science, Technology and Industry Scoreboard 2009," 6.

[40] For example, spillovers from company-funded basic research are very high—over 150 percent according to one study: Albert Link, "Basic Research and Productivity Increase in Manufacturing: Additional Evidence," *The American Economic Review*, 71, no. 5 (Dec. 1981): 1111–1112.

[41] Raymond Wolfe, "U.S. Business Report 2008 Worldwide R&D Expense of $330 Billion: Findings from New NSF Survey," National Science Foundation, 2008.

[42] Barry Bozeman and Albert N. Link, "Tax Incentives for R&D: A Critical Evaluation," 24. *Research Policy*, 13, no. 1 (1984): 21–31.

Senator KLOBUCHAR. Those were great ideas. Thank you, Dr. Atkinson.

Mr. Ubl.

STATEMENT OF STEPHEN J. UBL, PRESIDENT AND CEO, ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

Mr. UBL. Thank you, Madam Chair, Ranking Member LeMieux, Senator Begich, for the opportunity to testify today.

Senator Klobuchar failed to mention I'm also from Minnesota, which is——

Senator KLOBUCHAR. Well, I was trying to hide it, because——

Mr. UBL. Yes.

Senator KLOBUCHAR.—it meant we had two——

Mr. UBL. Two proxies——

Senator KLOBUCHAR.—Minnesotans on the panel. And so, I was——

Mr. UBL. All right.

Senator KLOBUCHAR.—trying to—I was deep-sixing it. No, it's fine; I'm kidding.

Mr. UBL. We appreciate your strong leadership and support of our industry, and look forward to continuing to work with you.

This hearing is particularly timely. The *Financial Times* reported, this weekend, that, after 110 years of world manufacturing leadership, the United States is about to lose first place to China. While manufacturing, generally, is faltering, the U.S. medical technology industry still leads, but our continued leadership cannot be taken for granted.

I'd like to make three points today, which are discussed in greater detail in my written testimony.

First, the medical technology industry is an American success story, both for patients and for our economy. And the potential for this industry, going forward, is enormous. For patients, medical progress has been remarkable. Between the period of 1980 and 2000, life expectancy has increased by more than 3 years. Deaths from heart disease have been cut in half. Stroke has been reduced by 30 percent, and breast cancer reduced by 20 percent.

For the economy, we are a true high point in the landscape of American manufacturing. We create high-paying jobs; 38 percent higher pay, on average, than jobs in the economy as a whole. As you mentioned, employment in our industry is growing, up 20 percent between 2005 and 2007. And we are one of the few manufacturing sectors that has consistently been a net exporter. And the future opportunities are enormous. Advances in the understanding of human biology open the door for dramatic progress in new treatments and cures.

The aging of the world population will create steadily increasing demand for medical progress, and the projected large growth of middle-class populations demanding modern healthcare in countries like China and India offer incredible opportunities for growth and export expansion.

Second, while America is the world leader in medical technology today, this leadership is by no means assured, and the trends are not positive. Since 1998, the surplus of exports over imports has been cut in half. Our member companies are increasingly intro-

ducing breakthrough products abroad before they're available to patients here at home. The proportion of clinical research trials conducted abroad has also grown dramatically.

Both FDA approval and Europe's CE Mark provide a gateway to developing markets, such as China and India. Our concern is that, over time, a more efficient European regulatory system could make it more attractive to locate R&D and manufacturing outside of the U.S. Venture capital investment in medical technology, as has been referenced is increasing faster in Europe today than it is in America.

At the same time these negative trends are occurring, foreign governments are putting in place aggressive policies to support their domestic industries and lure foreign investments, including favorable tax treatment, direct subsidies, failure to enforce IP protection for American firms, and manipulation of regulatory and payment policies to favor domestic research and production.

Finally, my third point is that we need to recognize that government policies have a tremendous impact on whether or not the United States retains its leadership in medical technology. These include regulatory, reimbursement, tax, trade, research and innovation policy. All are key factors in determining the future success of our industry.

I would especially like to highlight the central role of the FDA regulatory policies. FDA policies must protect the public health, but they must also encourage the medical innovation that is critical to patients and American industry.

One policy issue deserves special mention: FDA's reexamination and potential reform of the 510(k) process. This process fosters rapid incremental innovation for products with a low to moderate level of risk. It has an excellent track record in protecting public health. It would be a serious mistake, in our view, to make radical changes in the process that would undermine these strengths. Reform should be targeted on product types where there are documented problems, and should be reasonable and clearly designed to fix these problems within the structure of the 510(k) process.

At the same time, there are changes that could be made that would be clear improvements. FDA needs to provide greater clarity and transparency in evidence requirements through more guidance documents. This will help both manufacturers and reviewers, and will increase public confidence in FDA decisionmaking.

FDA also needs to work internally on increasing the consistency of decisionmaking and training of its reviewers. I know that the new team at FDA is committed to making the process work better, and I am hopeful that they will listen to, and respond to, industry concerns.

Madam Chair and all members of the Committee, thank you again for the opportunity to testify this afternoon. For America to lead in the 21st century, we must recognize that success will not just happen; it requires the creation of a positive "innovation ecosystem" that will capitalize on our industry's strengths and create a level playing field with foreign competitors. We believe the opportunity is great. The time to act is now.

And thank you very much for your time and attention.

[The prepared statement of Mr. Ubl follows:]

PREPARED STATEMENT OF STEVEN J. UBL, PRESIDENT AND CEO, ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

Thank you, Chairwoman Klobuchar, for the opportunity to testify on this important topic. My name is Steve Ubl, and I am the President and CEO of the Advanced Medical Technology Association (AdvaMed). AdvaMed is the world's leading trade association representing manufacturers of medical devices and diagnostics. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

We are very appreciative of this subcommittee's interest in the issue of the competitiveness of the life sciences industries. While today the U.S. is the recognized world leader in medical technology and the other life sciences industries, its continued leadership is by no means assured. A number of factors, including policies of foreign governments designed to support medical technology, threaten to undermine U.S. leadership and competitiveness. If America fails to lead in medical technology in this century of the life sciences, America's long-term future as the world's most powerful economy will be jeopardized.

Several characteristics of our industry are especially relevant as policies are considered to support the continued preeminence of the American medical technology industry. It is important to recognize that small firms are a key part of our industry. A 2007 study by the U.S. International Trade Commission (USITC) found a total of 7,000 medical technology firms in the U.S.[1] The U.S. Department of Commerce estimated that 62 percent of these firms had fewer than 20 employees and only 2 percent had more than 500.[2] Even large companies in the medical technology space tend to be smaller than large companies in many other sectors. There are only four pure device and diagnostic companies in the Fortune 500 and none in the Fortune 100.

Small, venture capital funded firms are particularly critical to the future of U.S. scientific and technology leadership, because they are the source of most of the breakthrough technologies that drive medical practice and industry growth. The National Venture Capital Association has developed an impressive list of breakthrough medical devices and diagnostics that were initially developed by venture capital funded start-ups, ranging from Doppler ultrasound to implantable defibrillators to pulse oximeters.[3]

Whether created by large or small firms, medical technologies are characterized by a very rapid innovation cycle. The typical medical device is replaced by an improved version every 18–24 months.

High levels of research and development (R&D) expenditures are necessary to continue this virtuous cycle of innovation and maintain U.S. competitiveness. As reported by the USITC, research and development is one of the main reasons for the US's competitive advantage. U.S. medical technology firms spent over twice the U.S. average on R&D. The USITC found that high technology medical device companies devote upwards of 20 percent of revenue on R&D.[4] The European Commission reported that U.S. medical technology firms' R&D expenditures as a percentage of sales were, on average, roughly twice as high as such expenditures in the EU and Japan as of 2005.[5] There are indications, however, that this differential is eroding.

The device industry is highly competitive, and this helps moderate U.S. healthcare costs. A study of medical device prices from 1989 to 2006 found that they increased, on average, only one-quarter as fast as the MCPI and one-half as fast as the regular CPI. Because the highly competitive market kept prices low, medical devices and diagnostics accounted for a relatively constant 6 percent of national health expenditures throughout the eighteen year period despite a flood of new products that profoundly changed medical practice.[6]

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[1] United States International Trade Commission, "Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets," March, 2007.

[2] U.S. Department of Commerce, unpublished data, 2002.

[3] Michaela Platzer, *Patient Capital: How Venture Capital Investment Drives Revolutionary Medical Innovation, 2007*.

[4] USITC, "Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets," March, 2007.

[5] *Ibid.*

[6] Donahoe, Gerald and King, Guy. "Estimates of Medical Device Spending in the U.S." May, 2009. Available from: *http://www.advamed.org/NR/rdonlyres/6ADAAA5B-BA37-469E-817B-3D61DEC4E7C8/0/King2009FINALREPORT52909.pdf*.

A key feature distinguishing medical technology from many other manufacturing sectors is the extraordinary impact of Federal policies. All medical technology products sold domestically are regulated by the Food and Drug Administration (FDA). Most must receive clearance or approval before they can be marketed and all are subject to quality systems and good manufacturing practices regulations. Further, products are monitored for adverse events once marketed to the public and are subject to recall authority. Accordingly, FDA policies are critical to the health and growth of the industry.

Beneficiaries of government programs are important consumers of medical technology. In 2008, Medicare and Medicaid together paid for medical care that accounted for 48 percent of total domestic sales of medical technology products. Patients in the VA and DOD care systems are also major users of medical technology. Meeting the coverage rules of these programs is critical for medical technology companies, given the size of this market, and their reimbursement policies ultimately affect a major share of company revenues. In addition, Medicare coverage decisions and payment methodologies often spillover to the private insurance market, expanding the impact of government decisions significantly beyond the boundaries of the government programs.

The manufacture of medical technology is an American success story. Our industry employs more than 400,000 workers, and, if indirect employment is included, the employment impact is substantially higher.[7] Industry pay levels are 38 percent higher than average pay for all U.S. employment and 22 percent higher than other manufacturing employment.[8] While the number of manufacturing jobs was plummeting across the larger economy, even before the current recession, employment in our industry was expanding. Between 2005 and 2007, medical technology employment grew 20.4 percent, adding 73,000 jobs.[9] During the recession, between 2007 and 2008, MedTech employment dropped 1.1 percent, compared to 4.4 percent for manufacturing as a whole.[10]

With $33 billion in total exports in 2008, medical technology ranks eleventh among all manufacturing industries in gross exports.[11] Notably, unlike virtually every other sector of U.S. manufacturing, medical technology has consistently enjoyed a favorable balance of trade. With the aging of both U.S. and foreign populations, the projected explosive growth of large middle class populations demanding modern health care in developing countries like China and India, and the accelerating pace of biomedical discovery, the potential for growth of our industry is great.

The contribution of the life sciences to our economy goes beyond conventional measures of employment, wages, and exports. By improving the health of the population, progress in the life sciences is an engine driving productivity and labor force participation, both significant contributors to economic growth and GDP. Between 1980 and 2000, medical progress added more than 3 years to life expectancy. The death rate from heart disease was cut in half; the death rate from stroke was cut by one-third, and the death rate from breast cancer was cut 20 percent.[12]

The Milken Institute has compared two alternative futures regarding the growth in chronic disease. Under one path, the current trends in growth in the incidence of chronic disease continue unchecked. Under the other path, the growth is reduced significantly by a combination of better prevention, better management, and continued technological progress in treatment. The difference between the current trend path and the more favorable path was estimated to be $1.1 trillion in GDP annually by 2023.[13] Similarly, the United BioSource Corporation examined the literature on the economic burden of lost productivity due to eleven chronic and two acute conditions. They concluded that the total drain on the Nation's GDP in 2008 from lost

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[7] The Lewin Group, "State Economic Impact of the Medical Technology Industry," June 7, 2010.

[8] *Ibid*.

[9] *Ibid*.

[10] *Ibid*.

[11] The Manufacturing Institute, "The Facts about Modern Manufacturing," 2009, p. 18; ITC data web.

[12] MEDTAP International, Inc.. The Value of Investment in Health Care: Better care, better lives, 2004, Bethesda, MD: MEDTAP.

[13] Ross DeVol and Armen Bedroussian, with Anita Charuworn, Anusuya Chatterjee, In Kyu Kim, Soojung Kim and Kevin Klowden. *An Unhealthy America: The Economic Burden of Chronic Disease*, the Milken Institute, October, 2007.

productivity and labor force participation due to these conditions was as much as $1.4 trillion annually in 2008.[14]

While the medical technology industry is a genuine American success story, our world leadership is not guaranteed to continue. Without sound public policy, it is increasingly likely that the U.S. will fall behind not only in medical devices and diagnostics but in other industries based on the life sciences.

To quote Dr. Laurence Summers, Chairman of the National Economic Council, "The 20th century was an American century in no small part because of American leadership in the application of the physical sciences. While the foundational ideas of relativity and quantum mechanics were developed in Europe, the practical application of these ideas occurred in the US. If the 20th century was defined by developments in the physical sciences, the 21st century will be defined by developments in the life sciences. It is natural to ask whether the U.S. will lead in the life sciences in this century as it did in the physical sciences in the last. It is a profoundly important economic question, but one whose implications go far beyond to embrace issues of national security and moral leadership." [15]

There are a number of indicators that show that the gap between America and foreign competitors in the medical technology industry is narrowing. While the U.S. has maintained a favorable balance of trade, the surplus of exports over imports has been narrowing both in absolute terms and relative to the size of the export-import sector. In 1998, imports and exports together totaled $24.6 billion and the trade surplus was $6.6 billion—more than one-quarter of total trade. By 2009, total trade had almost tripled—to $63.5 billion, but the trade surplus had shrunk by more than half—to $3 billion, and the surplus was only 4.7 percent of total trade.

A troubling trend is the rapid movement of clinical research abroad. In 2004, 78.7 percent of all clinical trials listed in *ClinicalTrials.gov* were carried out in the U.S. By 2009, that proportion had sunk to 45 percent. U.S. clinical trials that were specifically for medical technology products started even higher and finished even lower, dropping from 86.9 percent of the worldwide total to 44.8 percent during this period. The cumulative annual growth rate of U.S. clinical trials 2004–2009 was lower that of Brazil, China, France, Germany, India, the U.K., Israel, and Japan.[16]

Given the importance of startup firms in creating breakthrough technologies and fueling the growth of the industry, America's strong network of venture capital firms with an interest in investing in the life science has been a key strength. Here, too, although the U.S. maintains a strong lead in absolute terms, the lead is shrinking relatively. Comparing 2000 and 2009, venture capital investment in medical technology grew almost 60 percent in Europe and Israel and less than 40 percent in the U.S.[17]

Not only is venture capital growth in the U.S. slower than abroad, we are increasingly hearing that growing regulatory and payment uncertainties in the U.S. are causing VC firms to rethink whether they want to invest in the sector. Moreover, as they see longer time—and thus greater cost—in getting products to market as the result of these uncertainties, they are planning to invest the same amount of dollars in fewer companies and shifting investments more to companies that are further along in the development process.[18] If these trends prove durable, they would be very troubling for the future of medical innovation and for the industry. Moreover, there are far more start-ups seeking VC funds than there are funds available, suggesting that significant innovation opportunities are being lost.

Another troubling trend is that many AdvaMed members are increasingly looking to Europe to launch their products, given the longer regulatory process in the US. As the USITC reported "*an efficient regulatory approval system is an important factor favoring the medical device industry in the EU." [19] This observation applies not just to medical technology designed to be used in the EU but increasingly to third countries as well. For example, China now requires approval in the country

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[14] United BioSource Corporation, The Economic Burden of Chronic and Acute Conditions in the U.S., 2009. Available at *http://www.advamed.org/NR/rdonlyres/92EABCBA-4A06-4712-BFF0-1EE90C119876/0/A28690BurdenofDiseaseReport_Final_81409_CLEAN_Rev1.pdf*.

[15] Lawrence Summers, "America Must Not Surrender Its Lead in Life Sciences," *Financial Times*, January 28, 2007.

[16] *Clinicaltrials.gov.* PwC analysis.

[17] Data from Ernst & Young.

[18] Ernst and Young, *Pulse of the Industry: Medical Technology Report 2009*; Batelle Technology Partnership Practice, *"Gone Tomorrow? A Call to Promote Medical Innovation, Create Jobs, and Find Cures in America,"* report prepared for the Council for American Medical Innovation, June 10, 2010.

[19] United States International Trade Commission, "Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets," March, 2007.

of origin. So, to the extent the EU process is more efficient, medical technology approved in Europe has an edge over the U.S. in China. Likewise, many other countries in Asia and Latin America use approval in the EU or U.S. as the basis for market access to their market, favoring the more efficient EU system. Australia is another case in point, as its regulatory system is based on the European system, thereby expediting approvals.

The fact that products are launched first abroad has several negative consequences. From a human point of view, it means that American patients may be denied timely access to the newest and best treatments. From a commercial point of view, as more and more products are launched first abroad, there is a real danger that R and D establishments will follow, so that product development will be close to the first users of the product.

Foreign countries are working to undercut America's leadership in a number of ways that transcend the regulatory system. Many European countries offer a wide range of incentives to attract job-creating industries. For example, France dedicates funding equal to 2.2 percent of its GDP to programs designed to foster innovation and R&D—such as research tax credits, incentives for start-ups, Federal subsidies, as well as an additional $50 billion grant program about 10 percent of which is specifically dedicated to health and biotech research. Germany has committed about $1.5 billion to life science research, as well as special cash payments—some covering as much as 50 percent of costs—and grants to attract investment. The U.K. offers a variety of R&D tax credits, special schemes to support job-creating capital investment, and a new Office of Life Sciences specifically designed to involve the highest levels of government in cutting red tape, attracting clinical research and expediting the use of innovative medical technology. Ireland's multiple incentives have attracted over 90 separate medical device companies (including 15 of the world's top medical device firms), according to the USITC. Moreover, the European Commission offers its member states additional incentives to help attract job-creating industries as part of its "Framework Programmes," in which healthcare related industries are specifically identified.

Of course, Europe is not our only competitor, and other governments are eyeing the medical technology industry to bring jobs to their people. They are adopting policies to achieve this. For example, China has implemented an Indigenous Innovation policy in its government procurement—which could well include the vast public hospital sector—that is intended to require purchases of products with "domestic" intellectual property and to force the transfer of technology to domestic companies. Brazil's health minister has publicly proclaimed that he will use Brazil's product approval regulatory agency to favor domestic medical technology firms. India is building a series of industrial parks expressing to attract medical technology investment and the jobs that foreign companies will bring.

In the face of the negative trends noted above and the aggressive policies undertaken by foreign governments to build domestic industries and attract investment from multinationals, what should be the American response? In my view, we need a proactive program to assure that the U.S. retains its commanding lead in medical technology and all the life sciences. We need a program that will allow America to take full advantage of the enormous growth opportunities for medical technology in the 21st century. We need a program that will maximize the industry's contribution to the President's goal of doubling exports within 5 years.

The comprehensive approach I believe is necessary will include regulatory policy, reimbursement policy, trade policy, tax policy, and policies to support research and development. AdvaMed will continue to develop policy recommendations for the Committee. Today, I can share with the Committee a few ideas for your consideration. I hope we can work together over the coming months to positively shape the direction of U.S. policy and assure America's continued leadership.

Regulatory Policy

The predictability and speed of FDA decision-making, as well as reasonable, risk-based standards of evidence to show the safety and effectiveness of medical technology products is essential to maintain innovation and the long-term success of the medical device industry. The FDA clears products for marketing by one of two routes—the 510(k) process or the Pre-market Approval (PMA) process. The 510(k) process clears products based on their similarity to products that are already on the market and is not available to the highest risk products. To be cleared under the 510(k) process, a product must be "substantially equivalent" to a product already on the market, and manufacturers must demonstrate that the product is as safe and effective as the marketed product. If it has different technological characteristics or a different intended use than the product already on the market, the device manufacturer must present data to show that the product does not "raise new questions

of safety and effectiveness." The FDA has broad discretion to require any data that it thinks necessary to assure the safety and effectiveness of the device, including clinical data.

The 510(k) process is critical to a vibrant and successful device industry and to the process of medical innovation that provides better products for patients to address unmet clinical needs. In a typical year, 3,600 new products will be cleared for marketing through the 510(k) process. This compares to 30–40 products annually approved through the PMA process.

The FDA is currently conducting a thorough review of the 510(k) process with a view to instituting internal reforms by early September. The IOM has also been asked to review the process and will be making recommendations next year as to any changes it thinks are necessary. The device industry welcomes this review, because we believe the process can be improved and that public confidence in it can be increased. In this regard, we have contributed a number of ideas to the FDA and are pleased that they are being given careful consideration by the Agency leadership.

We also believe, however, that the 510(k) process has an excellent record of protecting the public against unsafe or ineffective products while providing a relatively speedy path to development and approval of innovative products. It is very important to the future of the industry and to continued medical progress that the 510(k) not be altered radically in a way that would unnecessarily increase the time and cost of developing new products.

The PMA process is reserved for products that are most innovative and of highest risk. PMA products are typically required to provide clinical data and often required to conduct a controlled trial of a new product. Development and testing of a PMA product is inherently costly, but the time it takes FDA to complete the review of a product is troubling. According to FDA data, in 2007—the most recent data available—the average time between a product's submission and a final decision by the FDA was 446 days. The device industry entered into a user fee agreement with FDA in 2002 in part to reduce the long time it took to complete a PMA review. Between that time and 2007, however, the average time in review actually increased by 2 months.

The figures cited above reflect total time between submission of a product to FDA and an FDA final decision. This is the most important metric for industry. As part of the user fee agreement, however, FDA has committed to achieving review time goals based on time on the FDA clock—that is time in which the FDA is actively reviewing a product. This time clock stops whenever the FDA asks the company for more data or clarifying information and restarts when it is supplied by the company. We have relatively current data for time on the FDA clock, and it shows that the FDA is not meeting its own review goals. We are pleased that the FDA leadership has made correcting this problem a priority and hope that the newest data will show an improvement.

Finally, the FDA recently put out draft recommendations to increase transparency of its operations. Transparency is clearly a laudable objective. FDA's recommendations are well-intentioned and, in some cases, meritorious. We are very concerned, however, that some of the recommendations dealing with release of information on products that are in the review process and cannot be legally marketed will undermine intellectual property and discourage investment in breakthrough products while providing no significant public health benefits. We hope that the final recommendations will address these concerns.

As I noted earlier, it is not a good omen for the future of the U.S. device industry—or for American patients—that an increasing proportion of complex products appear to be undergoing clinical trials and entering the market abroad before they are introduced in the U.S. The FDA leadership understands that promoting medical innovation is part of its mission to protect and improve the public health, and I am hopeful that FDA will find ways to speed up PMA reviews, maintain an effective 510(k) process and increase the predictability and consistency of reviews while maintaining its exemplary record of protecting patients against unsafe or ineffective products.

Payment Policy/Health Reform

A reliable expectation of adequate payment for products offering clinical benefit is a prerequisite for a healthy medical technology industry and for stimulating investment in technological innovation. The new health reform bill makes a number of changes in the way health care is paid for under Medicare that will, over time, create a profound shift in incentives throughout the health system. These changes are generally positive. Most policy analysts agree that the key to reducing growth in health costs and improving quality is to shift incentives in the health care system

toward rewarding value and away from simply paying on the basis of volume and cost.

While these new payment paradigms offer the promise of a more efficient and effective health care system, there are also some potential pitfalls that could negatively affect innovation and medical progress if the new systems are not carefully designed to encourage innovation.

The widespread adoption of an improved treatment or cure generally follows a typical path. The treatment is developed by a company or a physician. Following FDA approval (in the case of a drug or device) the new treatment is adopted by cutting-edge physicians and is recognized by insurance companies and other payers. If the treatment proves successful in practice, it gradually diffuses until it becomes the standard of care.

Without special protections for innovation, the new changes in health care delivery models and the application of quality standards to reimbursement risks freezing medical practice in place. New delivery models must ensure patient access to appropriate devices, diagnostics, and other medical technologies and must not penalize early adopters of new technology. The current quality standards are generally "process" standards—for example, for a given specific disease state, a certain course of action should be followed. For example, patients presenting with a heart attack are supposed to be treated with percutaneous coronary intervention (PCI) within 90 minutes. The new payment modalities embed these quality standards in the level of payment physicians and other providers will receive. Without special provisions in the reporting and payment system, providers who are early adopters of a new, alternative treatment—a new drug or procedure to replace PCI—will be penalized.

The same concern applies to adoption of new treatments that appear to be more expensive than the existing standard of care. Not only does the early adopter face a potential penalty on the quality side, but they also could be treated as inefficient because they are generating higher costs—even if the new treatment represents a significant clinical advance.

Providers could be penalized even if the new treatment actually lowers costs, if the savings appear outside the measurement window. For example, under bundled payments—where all providers treating a patient during an episode of care receive a single, lump sum payment—costs are measured across the episode of care. A drug-eluting stent that reduces costs over the long-term by reducing the need for repeat procedures would appear more expensive than a bare metal stent. So would a heart valve or a knee replacement that lasts for 20 years instead of 10 years or other treatments that have better outcomes over a more extended period than the immediate episode of care.[20]

These problems can be addressed without undercutting the central goals of payment reform. Possible solutions could include:

- Develop explicit design features to ensure Medicare health care delivery demonstrations and pilots protect patient access to appropriate devices, diagnostics, and other medical technologies and must not penalize early adopters of new technology.
- Improving the existing new technology add-on payment that is part of the current system by which hospitals are reimbursed for treatment of each Medicare patient and applying a revised version to the new payment modalities. Under the new technology add-on payment provision, hospital reimbursement for patients treated with a new technology that offers the promise of a significant improvement in care and is more costly than current treatments is increased to partially reflect the increased cost of the new treatment. The increase is time-limited.
- Allowing a grace period during which new treatments that are alternatives to existing quality standards are pulled out of both the numerator and denominator in judging providers' performance.
- Applying a modified version of the outlier policy in the current hospital payment system to the new payment modalities, so that providers are not penalized for providing appropriate care to patients who need more expensive treatments than the norm. Under the outlier policy, hospitals receive an increase in payment for treatment of patients whose care is substantially more costly than the average patient with that diagnosis.

[20] None of the payment schemes address economic benefits from effective treatment that arise outside the health system, from reduced disability, expanded productivity, and reduced dependency.

Building Innovation Into Government Policy

The discussion of the importance of considering the impact of payment and regulatory policy on innovation suggests another approach to stimulating the competitiveness of the life sciences sector. As agencies carry out their individual missions, most do not consider the impact of policies on medical innovation as part of their mission. As discussed earlier, the new payment paradigms created by health reform could have a profound and negative impact on medical innovation. These negative impacts can be avoided without doing violence to the goals of health reform. But to make sure the changes support rather than inhibit innovation, someone has to be thinking about the issue and build appropriate measures into implementation.

One option for assuring that innovation is considered as policies are implemented across the government would be to create a dedicated, adequately staffed office within the White House with the specific mission of making sure that government policies are sensitive to medical innovation and support the President's goals of assuring that America leads the world in science and technology. The office's activities would be complementary to the current work of OSTP and PCAST. This office would act as an advocate for innovation, provide review and input into policies of individual agencies, and serve as a point of contact for industries, institutions and individuals with an interest in medical, scientific and technological innovation. Such an office could be located within PCAST, OSTP or the National Economic Council, or could be a stand-alone office. This proposal has recently been endorsed by the Council for American Medical Innovation, a coalition of leaders and organizations from research, medicine, academia, industry, and labor.

A related policy that could be considered is to require that each major policy decision or regulation include an analysis of the impact of the policy on medical, scientific and technological innovation. This would be analogous to an environmental impact statement. Requiring that a statement of this kind be included would assure that the issue of innovation is at least considered as policies are developed.

Trade Policy

The opportunities for export growth by our industry and corresponding job creation in the United States are very great. Rapid economic growth in emerging markets is 2–3 times faster than in the U.S., EU and Japan. China's middle class is projected to exceed the entire U.S. population by 2015, and India's middle class could reach 600 million by 2025. These are just two of the largest expanding markets, with smaller but also rapidly growing economies in Southeast Asia, Latin America, and the Middle East. In each of these countries, the emerging middle class is demanding first class medical care and creating a very large potential market for advanced medical technology. Even in Europe, the market for many advanced technologies is historically under-penetrated.

The question is whether the U.S. medical technology industry will retain its leadership position to take advantage of this growth overseas and expand exports and create jobs for Americans. The future seems far less secure in view of the increasing competition by foreign companies and, perhaps more significantly, by foreign governments. Overseas, we see government policies that are designed to encourage domestic growth in, and attract foreign investment to, the medical technology industry. In the U.S., we need a comparable response.

As I have mentioned, there are significant efforts by a number of foreign governments to support a home-grown medical technology industry or to encourage location of research or manufacturing facilities or purchase of locally manufactured components by multinationals. Some of these efforts are legitimate, but others represent abuse of government power. Opening markets and ensuring a level playing field are essential to the future growth of the U.S. medical technology industry. Protection of American intellectual property is particularly vital. We are pleased with the support our industry has received from U.S. agencies involved in trade—the USTR, Commerce and State. The officials in these agencies have worked hard to use the tools they currently have to attack discriminatory practices in other countries.

But they need more firepower to match the efforts of other countries. U.S. trade barriers are very low—virtually non-existent for medical technology. Other countries, especially the fast growing emerging markets, have much higher access hurdles. Unless the U.S. becomes engaged in actively negotiating and implementing free trade agreements (FTAs) that lower those barriers, U.S. exports will suffer. The EU has many more FTAs around the world than the U.S. China is pursuing FTAs with its Asian neighbors. The barriers that U.S.-made medical technology must overcome drives up the cost of our products in foreign markets compared to domestically made products and even medical technology from their FTA partners.

The proposed Trans-Pacific Partnership (TPP) should be viewed as one important component of the Administration's export promotion for the medical device industry.

Implementing the U.S.-Korea FTA should be another, followed by launching many more FTA negotiations. In addition to the direct benefits from the specific provisions of the agreements, each FTA provides a valuable forum for governments to discuss and resolve trade issues. In a highly competitive global market, the United States cannot afford to disengage, as other nations conclude preferential agreements that benefit their industries. U.S. leadership in international trade is always necessary to maintain open markets; at no time has this leadership been more critical than in today's challenging economic environment.

In pursuing free trade agreements, it is important that the U.S. demonstrate a commitment to the strongest possible FTA provisions. In addition to advancing public health and patient access, these agreements should: (1) address non-tariff barriers (NTBs) affecting our industry, especially non-transparent or discriminatory regulatory procedures; (2) include provisions that foster access of foreign consumers to innovative products; (3) encourage harmonization among the signatories of regulations that are necessary for determination of safety and efficacy, consistent with international norms; (4) ensure the strong protection of intellectual property (IP) rights; (5) secure the most expeditious elimination of tariffs possible; (6) grant efficient regulatory approvals, while ensuring product safety; and (7) provide expeditious customs clearance. In addition, new FTAs, like the TPP, should include specific provisions for sectors, like the medical technology industry, to address our unique concerns regarding regulatory approvals and government reimbursement.

We recognize that negotiating new free trade agreements is a long-term process and can only focus on a limited set of countries. In the meantime, the United States is facing ever-greater challenges to its economic position in the world, and U.S. industry is experiencing fiercer competition in the global market place. Companies can deal with the challenges that come from the private sector and that are unaided by foreign government support. However, as I have noted, foreign governments are increasingly assisting their industries, sometimes directly but more often indirectly—for example by championing certain industries and adopting standards and regulations that favor domestic firms—and that are not consistent with international norms. Such actions that are used to protect the domestic market can have a damaging effect on U.S. exports to those markets, diminishing the U.S. manufacturing base. Therefore, we encourage the U.S. trade agencies to address the goals described above through all means at their disposal.

In that regard, we have two additional suggestions. First, in negotiations with foreign governments to preserve and expand export opportunities for U.S. manufacturers, USTR must have sufficient authority to lead negotiations involving these issues. U.S. agencies with regulatory authority should not have the option of opting out or adopting a posture of only protecting their authority within the U.S. There should be creative ways to maintain and strengthen regulations that protect the health and safety of Americans while improving the U.S. economy.

Second, we believe that one of the goals of regulatory agencies should be to improve U.S. international competitiveness. For example, the primary role of FDA is, and should certainly remain, to protect the health and safety of the American people. At the same time, consistent with that role, FDA should also assist U.S. international commerce. As it now stands, FDA's international mission is almost exclusively focused on assisting other countries to meet U.S. regulatory requirements—including by establishing offices in many of those countries. This legitimate outreach has the effect of facilitating access to the U.S. market in competition with U.S.-based firms. To maintain balance and help assure reciprocity, those same FDA offices should be staffed and have a mandate to work, in cooperation with the U.S. embassy, with foreign governments to assist entry of safe and effective American products into foreign markets.

Tax Policy

As is well recognized by authorities in the field, a number of aspects of American tax policy are not conducive to maintaining America's lead in science and technology or in encouraging medical technology and other industries to locate manufacturing and research and development in the United States. Issues that have been identified include the relatively high American corporate tax rate; the failure to make the R& D tax credit permanent and its lack of generosity relative to competitor nations; and tax policy that makes it expensive to bring profits earned abroad home for investment in America. All of these policies deserve reconsideration.

The R&D tax credit deserves special mention. The U.S. was the first country to establish such a credit, but today it ranks 17th out of 21 OECD companies in its generosity. It has been estimated that raising the credit from 14 percent to 20 percent would increase economic output by $90 billion and increase Federal tax reve-

nues by $90 billion, more than offsetting the $6 billion of additional Federal costs.[21] The failure to make the credit permanent undermines its ability to stimulate research and development, as opposed to subsidizing research and development that would occur anyway. For the start-up companies creating the breakthrough products of tomorrow, the R&D tax credit has limited utility, as described below, and could be much more effective in encouraging innovation.

The newly enacted $20 billion excise tax on medical technology products will inhibit investment and put U.S. domiciled companies and especially small companies at an additional disadvantage relative to foreign competitors. Of course, we want to express our deep appreciation of your successful efforts, Senator Klobuchar, to reduce the level of that tax.

Encouragement Of Small and Start-Up Companies

As discussed earlier, small and start-up companies are critical engines of innovation for the medical technology industry. These companies are extremely dependent on venture capital and angel investors and sufficient venture capital is often not available to fund many promising ideas, to provide support in the earliest stages of product development, and to sustain development of innovative products over an extended timeframe. There are several ideas that could be considered to address this problem that could potentially have a significant effect in driving scientific and technological innovation:

- For companies with no profits, allow the R&D tax credit to be taken against payroll taxes or received as a refundable tax credit rather than held and used against future profits. This could help provide critical capital during the time when the company most needs a positive flow of funds, and could have a major impact in encouraging private investment and bringing more innovative therapies to fruition.
- Expand the Small Business Innovation Research program at the NIH and liberalize eligibility requirements. This program is potentially extremely valuable in funding early-stage research and development by start-up companies, but the maximum award size and the requirement that applicants can not have majority venture capital ownership are limiting. Since the program precluded awards to majority venture capital owned firms, applications for SBIR grants at the NIH have declined by almost 50 percent.[22]
- Expand support for regional or local innovation clusters and incubators. Such clusters have been shown to spur development of new technologies and products and additional support for local efforts to establish them could be helpful.

Invest in America's Science Base

America's science base, including basic research, the supply of scientists and engineers, and vitality of America's universities as centers of basic and applied research, is critical to the medical device industry, as it is to America's leadership in science and technology more generally. A number of studies have documented the relative decline of America's science base by such measures as R&D investment as a share of GDP, new patents as a share of the global total, global share of scientific researchers, and new doctorates in science and engineering.[23] The Administration's proposals, as outlined in the President's address to the National Academy of Sciences on April 27, 2009, will go a long way to rebuilding America's scientific and technical strength and these policies should be maintained.

Conclusion

Thank you again for your interest in this important issue. If I could leave you with one message it is this: to maintain America's world leadership in the life sciences generally and medical technology specifically, we need good policy to support our strengths in this increasingly competitive world.

Senator KLOBUCHAR. Thank you very much.
Mr. Weiss.

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[21] Robert D. Atkinson, "Create Jobs by Expanding the R&D tax credit," ITIF, January, 26, 2010, cited in *Gone Tomorrow*.

[22] *Gone Tomorrow*.

[23] Robert D. Atkinson, "Role the U.S. Government can Play in Restoring U.S. Innovation Leadership," testimony before the Committee on Science and Technology, Subcommittee on Technology and Innovation, U.S. House of Representatives, March 2.

STATEMENT OF ANDREW M. WEISS, PRESIDENT AND CEO, COAXIA, INC.

Mr. WEISS. Thank you very much, Senator Klobuchar, for inviting me to be a witness at this hearing. Senator Begich, Senator LeMieux, thanks very much for letting me come here and testify and represent our industry.

As you heard, my name is Andrew Weiss. I'm the President and CEO of a startup company named CoAxia. CoAxia is pioneering an innovative therapy to treat ischemic strokes. Ischemic strokes affect over half a million patients a year.

By way of background, I am an engineer. I did go to MIT. I did get a business degree. And I've spent most of my professional career working in, or guiding, medical device companies.

Today, in addition to my role at CoAxia, I'm on the boards of a couple of startup companies, and I advise others, and medical venture device firms. So, I live, sleep, eat, and breathe this every day.

I'm here to discuss my direct experience with what it takes to develop and commercialize medical therapies. And, as we've heard, you know, this industry, I think, is a shining star. I like to say to my community, "We're the good guys." We've helped with a positive trade surplus. We help improve, extend, and help people's lives. But, this industry's now at risk.

So, our community has developed pacemakers, implants, neurostimulators, minimally invasive surgery techniques, et cetera. All of these devices help people's lives. And many of the jobs in our industry are highly paid and very, very highly skilled. And, as you heard, in our hometown of Minneapolis there are hundreds of medical device companies, thousands of employees. We have a precious natural—national resource, where we can develop, test, and manufacture medical therapies for almost any disease state right here in Minnesota—or, right there in Minnesota.

So, let me tell you a little bit about the CoAxia story. CoAxia was started 10 years ago, by a brilliant neurologist at Cornell Medical Center, named Denise Barbet. Denise had an idea for increasing the blood flow into patients' brains after they got an ischemic stroke. She had a concept for treating these patients. She came to Minnesota, and she found guidance and venture capital money.

Since that time, I've raised $60 million for the company. We've conducted five clinical trials in over 10 countries, at 80 medical universities and research centers. We've employed dozens of people. We've recruited the efforts of hundreds of clinical researchers in these different institutions.

And we're not done. Although we finished enrollment in our pivotal trial, after 5 years of work, we're calculating, we're collecting lost data. We hope, if we're positive, to submit a PMA to the FDA sometime later this year.

After this 10 years of work, if we're positive with our PMA, we hope to then apply for coverage, coding, and reimbursement from CMS and the insurance agencies, and conduct a likewise process overseas, as well. So, you can see, from the startup of an idea, to actually getting a device into clinical use with reimbursement can take 10 to 12 years, $50- to $100 million.

As you can see, as a CEO of a startup, I'm at the intersection of many of the members of this ecosystem, and these members, in

many cases, don't know that they act, frankly, in partnership. So, my job is to coordinate them all.

And who are they? They're the patients, the physicians, inventors, universities, hospitals, regulators, engineers, clinical trialists, suppliers, and our investors, and lawyers. If these members aren't aligned, then the innovation process stops. So, fundamentally, our role is to make sure that the entire innovation process works as efficiently as possible.

This ecosystem's in great risk right now. Despite the fact that there's an unparalleled amount of new technology to apply to medical therapies, this whole community is threatened. The FDA regulatory environment is in flux. And this risk of increasing uncertainty, time to market, et cetera, is reducing venture investing in the community. Reimbursement paths are complex and opaque. Physician consulting relationships and access to university technologies are being restrained.

All of these factors, combined with the global financial downturn, has led—have led to significant declines in venture investing. The declines in venture investing are choking off the formation of new medical device companies. If these factors continue to trend negatively, our ability to innovate in this field will cease.

Let me highlight a few areas of great concern.

First of all, as we discussed, the regulatory environment. The FDA's mission is to establish reasonable safety and efficacy of medical devices, and to promote innovation. Demands for additional information, delays in reviews, questionable experience of reviewers, inconsistency in the application of FDA guidelines, and, as we've heard, the announcement of upcoming changes in the 510(k) process, causing concern in the medical innovation community. Dr. Shuren, the CDRH director, deserves a lot of credit for being public about the need, and for driving changes.

But, what's happened in the meantime is, venture investing in this field has frozen, in anticipation of the possibility of more restricted FDA guidelines, and they're causing U.S. companies, many of my colleagues, to shift to an outside-of-the-United-States strategy for both development, trialing, and commercializing. This is real, and it's happening today.

A clear, efficient, predictable regulatory path, which focuses on reasonable standards of safety and efficacy, will promote innovation in the United States. The medical community needs a champion to help with this effort, to make sure that the FDA is serving the balance of public good, here.

With regard to the financial community—this is the other major risk right now—in addition to the perceived regulatory risk, the global financial decline has led to a reduction in venture investing. And, as I mentioned earlier, this reduction in venture investing is negatively impacting startups.

Intellectual property reform is the third area. As it takes, often, more than 10 years to get a new invention out into clinical use, patent protection is critical. If we can't offer that to our investors, they won't invest in our companies.

And physician availability. It is critical that we have easy access to physicians to act as consultants to our companies, and, in some

case, in early stages, that we can use stock to remunerate them. We need access to physicians.

So, our medical innovation model is based on a public/private partnership. We look forward to your help. Thanks very, very much for inviting me here.

[The prepared statement of Mr. Weiss follows:]

PREPARED STATEMENT OF ANDREW M. WEISS, PRESIDENT AND CEO, COAXIA, INC.

Introduction

My name is Andrew Weiss, and I am the President and CEO of CoAxia, a medical device start-up company based in Minneapolis, MN. CoAxia is pioneering an innovative medical therapy for ischemic stroke, a condition that afflicts more that 500,000 Americans every year. By way of background, I am a mechanical engineering graduate of MIT with an MBA from Columbia University. I have spent the majority of my professional life leading large and small medical device companies, or participating on their Boards of Directors. I have run startups with no revenue and a $600M division of Medtronic. I have worked with medical capital equipment, diagnostic imaging, patient informatics, implantable device therapies, and single use catheter systems, with companies and investors in the U.S., Europe and Israel. Today, in addition to my role at CoAxia, I am a Director of two early-stage medical companies and am an informal advisor to others and to medical venture funds.

The U.S. medical device innovation engine—the medical device startup community—is at great risk. Despite an unparalleled level of new technology which is available to apply to medical therapy innovation, there is great concern in the medical community that our ability to pioneer new therapies is threatened. The regulatory environment is in flux. The financial system of venture capital is in a period of decline. Physician consulting relationships and our ability to collaborate with university hospitals are being restrained. Intellectual property laws are in review—possibly making it easier and cheaper for patent infringers. If these factors trend negatively, then our ability to fund, develop, evaluate and produce new medical therapies will decline. We need visibility to the issues, and in a number of areas, support from our legislatures.

Medical Device Industry Benefit

Let us remember for a moment the medical devices which save, improve or extend lives today—which are the result of medical innovation. Pacemakers. Hip implants. Stents. Angioplasty catheters. Neurostimulators for pain management and movement disorders. Of course the list goes on and on. They benefit patients. They are good for our society.

In addition, as you all know, the companies which make these devices employ hundreds of thousands of Americans. Many of these jobs are highly skilled and highly paid. They are the sources of income, taxes and community wealth across the U.S.. In my hometown of Minneapolis, there are hundreds of medical innovation companies and the entire business and clinical infrastructure to support them: suppliers, lawyers, consultants, clinical experts, physicians. It is an intensely valuable community of experts who can collaborate to develop new medical therapies. This is, in my view, a precious national resource.

In addition, U.S. medical devices are heavily exported and generate a $5B+ positive trade balance. Our technology and devices generate income for American companies and positive good will around the world.

Some say that medical device innovation raises healthcare costs. More tests, more scans, more procedures, yields more costs . . . However, innovation in medical therapies also improves patient outcomes, speeds their return to productive, healthy lives, reduces hospital stays, increases physician productivity and can reduce healthcare administrative expenses.

Lastly, some people have intimated that we have enough medical devices—and that there is no more need for medical therapy innovation. This is an absurd and dangerous point of view. There are many, many untapped fields of innovation in medical treatment, and we should in fact view this decade as having the possibility of a renaissance in medical innovation: genomics, nanotechnologies, higher levels of computing power, miniaturization, biotechnology, device combinations and more. To even consider our work "done" is a terrible injustice to citizens with illnesses and an unwise, cynical approach to innovation and progress.

Trends and Pressures—Medical Device Innovation at Risk

Positive trends—There are many positive factors in medical device innovation today—primarily due to technology: the explosion of new materials, electronic, biotechnology, genomic and communications technologies. As I mentioned earlier, the underlying development of new technologies is creating major new opportunities to manage care, provide treatment, and reduce costs. From simple technologies which allow the elderly to be remotely monitored for their heart conditions, to complex image-guided remote robotic surgery, to closed-loop methods to control insulin for diabetes patients, there are thousands of new devices and new therapies in development and ideas yet to come based on new technology development. Other positive trends have been the increasing use of information and computing technologies to speed and reduce the cost of development.

Negative trends/Increasing Risks—On the negative side there are a number of critical factors which deserve your attention. As one of my medical community colleagues Dr. Josh Makower has put it, the medical device community is facing "the perfect storm" of negative factors, which indeed threaten medical device innovation. The key negative trends are:

Regulatory environment—Within the FDA's mission are the requirements to establish the "reasonable safety and efficacy" of medical devices, and the "promotion of innovation." The division which regulates medical devices, the Center for Devices and Radiological Health (CDRH), has the responsibility to clear or approve all medical devices—an enormous task. Over the past 5 years thousands of devices have been cleared to market by the 510(k) process and a few hundred by the PMA process. A number of trends are causing concern among medical device innovators, including demands for additional information, delays in reviews, a perception of inconsistency, and announcements of upcoming changes to the 510(k) process. Dr. Jeffrey Shuren, CDRH Director, deserves credit for being very public in his efforts to upgrade and reform FDA practices, but in the device community, the anecdotes of delayed reviews, inconsistency, changing requirements and upcoming changes have caused deliberate shifts of venture funding away from medical devices. In my experience, this shift is due to fear among the venture investors that the regulatory requirements are unknown and increasing.

Financial community stability—At the same time, global financial instability, starting with the derivative and mortgage-backed security crises has forced significant reductions in funds going into the medical device venture funds. The impact is that venture investing is down ⅓, and a much higher proportion of the remaining funds is supporting existing companies, and moving away from early stage startups. As you can imagine—no funding—no innovation.

Uncertainty and complexity in healthcare structure, coverage and reimbursement—For years, the complexity of our healthcare insurance environment has challenged device innovators. Whereas we can relatively easily identify patient and clinical needs, determining insurance coverage, physician, hospital and clinic reimbursement paths is a constant challenge.

In summary, the medical device innovation community is threatened by a combination of longer and more expensive development and clinical requirements, increased regulatory burden and risk, uncertainty in the health coverage and insurance fields and more restrictive policies regarding hospital and physician collaboration. If we want a healthy medical innovation community, we must address these issues.

What Support is Needed Now

I believe, and many of my colleagues in the startup medical device industry believe, that we are in very challenging times for new medical device innovation. The combined challenges of regulatory uncertainty with threat of increasing data requirements, setbacks and uncertainty in the venture community, a long, complex and uncertain environment for medical device insurance coverage and payment and restrictions to access University settings and physician advisors are crippling our ability to fund, invent, develop, evaluate and bring innovations into clinical practice.

Medical Device Regulations—The U.S. regulatory device approval process is by definition complex and requires deep study for any true assessment of recommendations. The medical community needs a champion to assure that the FDA regulatory process becomes a clear, efficient partner in the medical innovation process—ensuring reasonable safety and efficacy *and* promoting innovation. The fundamentals are: a clear, efficient, predictable regulatory path, focusing reasonable standards for safety and efficacy, which align with the risk/benefit of medical devices, will promote innovation. Speed, predictability, least-burdensome principles and a partnering attitude with the ultimate goals of safety and efficacy are needed to ensure that U.S. medical innovations flourish here in the U.S.

A few basic principles are important:

- Innovation in medical devices needs a competent, clear, efficient and collaborative CDRH which partners with device developers to reach consensus on a strategy for technical and clinical data, which assures reasonable safety and efficacy of treatments *and* promotes innovation.
- The medical community needs the FDA, as its regulations and policies create a baseline for device and treatment safety, efficacy claims, reliability, and comparable clinical and technical evidence. This allows physicians, payers and patients to be able to compare, select, and have confidence in their treatment selections.
- Congress needs to provide guidance to the FDA on its fundamental role: is it chartered to select treatments for physicians, or to regulate approval of devices and treatments for physicians to select. It is my view that the FDA should clear/approve treatments, and then let the medical community select treatments based on their assessments of relative effectiveness and their patients' needs.
- CDRH must have the skills, expertise, structure, and guidelines, along with partnerships with the medical community to help judge the safety/risk/benefit balance of any new therapies.
- CDRH should ensure that any requests for additional information conform to the basic principle of being "least burdensome." CDRH's device evaluation information requirements scale based on device risk. This is appropriate and should be a basic principle for future assessments. Requests for additional data, tests and studies should only be those which are required to "assure reasonable safety and efficacy."
- There are times when studies come close to meeting but do not fully meet their trial objectives. The FDA should have the flexibility, and the encouragement, to allow treatments and devices to be approved for narrower claims based on these trials, with requests for appropriate follow-on studies, so that these devices can be put into clinical use without the need for completely new studies.
- CDRH needs to maintain, upgrade and streamline the 510(k) clearance process so that incremental improvements in devices can be moved quickly through the clearance process.

Financial community stability—The medical device industry needs stability in the financial community, healthy employment and healthy state and Federal Government budgets in order to have the private funds needed to support medical innovations. The current financial environment, combined with uncertainty about the FDA regulations has choked off investments into medical venture funds, which is further reducing medical device startups.

Coverage and Reimbursement—Medical devices innovators need a clear path to insurance coverage for its devices and procedures. The U.S. presents a complex patchwork of largely independent systems which review new devices and treatments for insurance coverage, coding and hospital, clinic and physician payment. The lack of efficiency, consistency and clarity in coverage and reimbursement prevents new therapies from clinical adoption.

Hospital/University partnerships—Medical innovators need access to university labs, people and resources. Many universities are facing conflicting pressures of intellectual property commercialization, restrictions on innovators or physicians from owning their inventions, or from being compensated as consultants to startups, and from academic conflict of interest guidelines to ensure that their professors' publications are deemed unbiased.

Physician availability—All medical innovators—and especially the smaller companies—need inventions, advice, feedback from, and research conducted by leading physicians in their fields. Without physician invention, we will lose most new medical therapy ideas. Without physician feedback, we will develop products which do not fit their needs. Small companies often do not have cash to pay physicians, and rely instead on stock or option grants as compensation. Physicians need to be able to invent—and own stakes in their own companies—and to consult—and be compensated for their work, without recrimination.

Summary

Medical device innovation is a positive, valuable resource for the United States. It is threatened by the combined forces of financial markets instability, lack of clarity and administrative burden from existing regulations and uncertainty about regulatory reform, patent reform, access to physicians and university resources and clarity and speed in insurance coverage and reimbursement. The industry welcomes congressional review and visibility into these diverse issues in order to continue to

prosper and to provide innovative medical therapies, jobs and positive export trade balances for America.

Additional Background Information

Medical Device Innovation—Collaboration Requirements

Medical Device Innovation requires many collaborating partners. In order for our system for medical device innovation to take place, key partners must collaborate productively. The key partners are:

I. *Inventors*—There are thousands of inventors in the U.S. and overseas. This vibrant community exists in companies, universities, hospitals and garages. They are motivated to invent, but require financial incentives and rewards to fund their livelihoods and work.

II. *Physicians*—Physicians are fundamental to the medical innovation process. They invent, guide, judge and adopt new therapies. It is in the public's best interest to have physicians intimately involved with, and incentivized to participate in development of new therapies. If physicians are restricted from participating in therapy innovation, then the innovation process will stop.

III. *Scientists and Engineers*—It goes without saying that our national competence in engineering and science is a basic requirement for medical innovation. We need strong universities, science and biomedical engineering scholarships and internships, and immigration for key talents.

IV. *Patients*—Everything we do is patient-focused, however, we also critically need patients to participate in clinical studies. Without them, we cannot determine safety or efficacy of new therapies.

V. *Universities*—Universities are key sites for labs and research facilities, generators of new technologies, education centers for future physicians and scientists, and magnets for inventors. University relationships with their research and teaching staffs should facilitate business formation and collaboration with the startup community.

VI. *Hospitals, Clinics, Physician Practices*—Hospitals and the related care providers offer the underlying resource to evaluate and then adopt new therapies. Overly restrictive risk profiles and intellectual property rules, or inadequate patient data management stifles new therapy evaluation.

VII. *The Financial Community*—The vast majority of medical device innovation is funded by private investors who take long term risks on the development and commercialization of new medical therapies. Whether they are private investors in large public companies, "angel" investors who seed startups, or venture funds who provide the core capital to prove out new therapies, each of these investors plays a fundamental role in medical innovation: they provide the capital which funds all the work. And, without the promise of a reasonable return for the risk taken and capital employed, then the financial resources will cease, and the new technology will stay just that: as new technology. It is important for the public good for there to be sufficient stability in the financial markets, clarity and transparency in medical venture investing, and a reasonable regulatory and reimbursement environment, if we are to continue to rely upon—and benefit from—private funding of medical device development.

VIII. *Regulatory Agencies*—All medical device innovators have the same underlying objective: to develop devices and therapies which are safe and serve a medical need. Only when a device meets these simple objectives is there any hope of medical adoption, insurance coverage and use—resulting in sales and profits. In the U.S., the FDA is responsible to regulating medical devices and therapies, for setting the standards for safety and efficacy, and for ensuring that medical devices meet their stated and proven claims, so that physicians and patients can make informed decisions about adoption. Medical device manufacturers need a clear, predictable, efficient, and appropriate regulatory path to clear and approve medical devices in order to both create realistic and timely plans to evaluate new devices, but also to minimize the time and cost to develop, evaluate and place devices into clinical use.

Note that the FDA has been in the news often these recent months, and the medical device community is very concerned about the recent trends. The fundamental issue is that all medical devices have some level of risk associated with them—and this risk must be balanced against the potential benefit of the therapy. If the risk-benefit balance is too lax, patients may suffer—but with good disclosure physicians will stop using the therapy. If the balance is too tight, no new therapies will be approved and then all patients who could possibly benefit

will be denied their opportunity for treatment. This balance is a ultimately a decision based on data and medical judgment, which is guided by two key FDA guiding principles: "reasonable safety and efficacy," and "least burdensome" paths to market. The concern in the innovation community is that current—and possibly the new—FDA policies are too restrictive, uncertain and unpredictable. In this case, we cannot plan, investors cannot invest, and our innovation cycle breaks down.

IX. *Insurers and Payers*—Without insurance coverage, coding, and appropriate reimbursement for devices, institutions and physicians, there will be no adoption of new medical therapies. Clear benchmarks for reimbursement and coverage processes provide innovators guidance for timing, pricing and costs.

How the Medical Innovation Collaboration Works

The medical innovation process is long, risky, and involves the diverse community mentioned above. To understand how to facilitate the process—to reduce risk, remove choke points, reduce time, and increase output, while maintaining the underlying goals of safety and efficacy—a quick review is valuable.

a. *Invention*—A new idea for a medical device or therapy is invented and the inventor often seeks advice from physicians. Some times the inventors are University employees. Often, the inventors offer physicians stock in their new company for their advice. The inventor will submit patent applications for their invention.

b. *Initial Funding/Prototyping/Animal Experiments*—The inventor and physician may raise some funds from local investor "angels"—perhaps as much as a few hundred thousand dollars—to develop prototypes and proof of principle of their therapy.

c. *Feasibility Testing*—After initial testing and prototyping—often 1–2 years from invention—the inventor may seek venture capital funding to build a team, conduct initial human experiments. $3M–$10M is raised, 20–30 employees are employed, more physician advisors are needed, University research hospitals are involved and 1–2 years passes. FDA approval of the studies—or work overseas—is required. Following the initial feasibility work, the team will often conduct a second set of feasibility trials, also under FDA approval, to refine their therapy, and demonstrate some level of patient benefit and safety. This second trial may also take 2–4 years and require $10M–$20M. The team may grow to support the development and manufacturing of devices and to conduct the trials—at perhaps as many as 10–20 hospitals.

d. *Pivotal Study*—The team must then conduct a pivotal study, which is also regulated with the FDA and establishes the specific claim language and statistically valid outcomes for the therapy. This pivotal study may involve hundreds of patients, take 3–5 years and cost $50M–$100M. Dozens of hospitals, hundreds of patients, and 50+ people are now engaged in the development, manufacturing and clinical work for the new therapy.

e. *Regulatory Submissions*—After the trial is completed, the team then submits trial results to the U.S. FDA and overseas regulatory/insurance groups. The FDA process involves FDA reviews, often review by an FDA-selected panel of physicians and then a final decision by the FDA. The entire time and cost of data collection, review, FDA submission and FDA review may take 2 years and $10M–$20M.

f. *Coding, Coverage and Reimbursement*—After FDA review and approval, the Company may now initiate sales and marketing, but must still secure insurance/CMMS coverage and reimbursement—and include hospital payments, physician payments and device payments—a 2-year process.

In the end, 10 years are likely to pass, 50–100 employees hired, $50–$100M dollars raised, 50+ hospitals, 100+ physicians, often 200–500–1,000 patients are studied, insurers and at numerous state and at least 2 Federal agencies have been involved. The time, commitment, development and investment in these new devices is extraordinary.

The process for new medical devices and therapies to be developed, tested and approved is a complex, long and risky path. Medical innovators—and the medical startup community have mastered this process and the new medical therapies in use every day are the result. This is good for America. And we can do better.

Senator KLOBUCHAR. Thank you.

Mr. Williams.

STATEMENT OF RHYS L. WILLIAMS, PRESIDENT, NEW WORLD ANGELS, INC.

Mr. WILLIAMS. Senator Klobuchar, thank you very much for convening this subcommittee hearing. And I want to thank Senator LeMieux, as well, for the invitation to speak as a witness, and thank Mr. Begich for his consideration.

Senator KLOBUCHAR. He's returning in a minute.

Mr. WILLIAMS. I believe you.

Senator KLOBUCHAR. I'll fill him in on what you say.

Mr. WILLIAMS. He knows where I live. I know where he lives.

Members of the Committee are likely very aware of the critical role that entrepreneurial management plays for one of our—for our Nation's competitiveness, and quality and quantity of innovative technologies, and the companies that our economy produces.

You may be somewhat less aware of the role of so-called "angel investors," who, in most years, either match or exceed the total level of early venture finance funding provided by institutional investors to early-stage ventures. These are the same companies that create new jobs in entirely new industries—high-wage jobs—for our economy, and assist our competitiveness.

Angels invest as much money as VC firms do, but in smaller amounts and spread over a greater number of companies, with—and also with a greater geographic dispersion of those companies. So, in that case, a very important source of financing, nationwide.

Angels may invest individually, in small groups of two or three fellow investors, or as part of structured angel groups, whose numbers may range from 20 to 25, giving them real critical mass, in terms of combining individual checks into meaningful financing rounds.

The prototypical angel investor—angel group investor—has been an angel for 9 years, has made an average of 10 angel investments during that time. They, themselves, have founded an—on average, 2.7 ventures over 14.5-year tenure as an entrepreneur; is 57 years of age, and has earned a master's degree; and commits fully 10 percent of their total net worth to investments within this asset class of early-stage investing. So, they're very familiar with the challenges and the opportunities within this asset class of early-stage capital.

Early-stage investment is critical to commercializing the technological innovations and promoting our Nation's competitiveness. And that should be obvious by now.

From both of these perspectives, that of entrepreneur and that of other—of angels that back them, there are several areas where the Federal Government can take positive action to increase and accelerate the quality and rate of our innovation.

I'd like to hit a couple of them. And I've been fortunate, most of the panelists have covered several of them, so I can, kind of, be very specific in certain comments.

With regard to the FDA, I'd like to make a very—a somewhat controversial suggestion that we might—the agency might shift away from a zero-defect mentality. And there's probably not enough time to fully go into that, but there are medications that provide significant benefits to a very broad number of patients, and yet there are certain profiles where they do present a hazard. This

can be diagnosed ahead of time. And with patient—with careful decision and oversight with physicians, there may be cases where we should look beyond just a zero-defect mentality within that agency.

With regard to the U.S. Patent and Trademark Office, we really need—there are very little incentives for our entrepreneurs to file in foreign—certain strategic foreign jurisdictions, because of the lack of enforcement and—or quality of enforcement. And it's unfortunate, because we thereby abandon any, really, economic value of the innovations that we come up with here in our country. So, we really would like the Federal Government to significantly push for protection, and particularly in strategic jurisdictions—China, India.

Federal tax policy is the one area I think where I can speak best to and is, I think, critical. The incidence of low capital gains rates over the past several years has definitely led to an upsurge over the past 6 years in early-stage investment. And so, low capital gains rates are very necessary to support an investment class which is characterized by 5- to 15-year holding periods, illiquidity up—all the up to the time of exit, categories of risk that are just not present in other asset classes, such as regulatory risk: Will you actually be able to sell the product that you have, and when? Technology risk: Will the product ultimately work, once we get the prototype developed and the product perfected? And financing risk: Will there actually be another investor to pick up the baton once we've done our part and handed it off? It's a very unique asset class, and it requires special protections. And among those protections, or promotions, is capital gains—a low capital gains rate. With the absolute number of angel investors able and willing to invest, and with—contracting on an absolute and relative basis, it's critically important that capital gains rates remain very low to extend investment in this asset class.

Same is true with the number of—number and extent of venture capital investments. The industry, as it normally does, is going through a significant contraction. The boom-and-bust cycle usually sees the ranks thin by two-thirds over the period of a cycle. And so, that industry, as well, is very dependent upon low capital gains for maximum returns.

I see my time is up. If I can take just one more minute?

Senator KLOBUCHAR. Sure.

Mr. WILLIAMS. Thank you very much.

Serious consideration needs to be given to the—removing the threat of taxation of carried interest. This is also—I think, will thin the ranks of venture capitalists. People—it will steer managerial talent out of the sector. Potential venture capitalists will seek employment in other areas, where compensation is much more lucrative. And current fund managers will retire. They, essentially, won't want to raise another fund. I have seen this firsthand. I've lived it through the—during the dot-com era. And so, our venture industry is the envy of the entire world. It is the goose that lays the golden egg, and we would be ill-served by threatening one of its key incentives, which is the carried interest, the taxation of carried interest. So, we need to, I think, leave well enough alone when it comes to taxation of that very important feature.

I went to thank you again for this opportunity. Unfortunately, I didn't get a chance to talk with other—on my other points, but they are in my remarks—my written remarks.

Thank you very much for this opportunity.

[The prepared statement of Mr. Williams follows:]

PREPARED STATEMENT OF RHYS L. WILLIAMS, PRESIDENT, NEW WORLD ANGELS, INC.

My name is Rhys Williams, and I would like to thank Sen. George LeMieux (R.—Florida) and the other Honorable Members of the U.S. Senate Subcommittee on Competitiveness, Innovation, and Export Promotion for this opportunity to share ideas from the frontlines of both entrepreneurship and early stage venture finance. I am a businessman from southeast Florida, and I wear two closely-related hats. My primary occupation is that of biotechnology entrepreneur; I am President of an early stage R&D firm (iTherapeutics) developing pharmaceutical drug candidates in partnership with academic researchers from the region's leading academic institutions. Additionally, my all-consuming avocation is serving as President of Florida's largest and only state-wide angel investor group (New World Angels), whose individual members invest collaboratively in what they hope will be the region's next entrepreneurial business success stories.

Members of the Subcommittee are very aware of the critical role that entrepreneurial management plays for our Nation's competitiveness and the quantity and quality of innovative technologies and companies our economy produces. They may be somewhat less aware of the role of so-called "angel investors," who, in most years, either match or exceed the total level of early stage venture funding provided by institutional investors such as venture capital funds. The Center for Venture Research estimates that U.S. angel investors invested $19 billion in 55,000 deals (in about 35,000 small businesses) in 2008. Figures for 2009 (same source) comparing the activity of angel investors with that of institutional venture capital funds is highly instructive. In that year, 259,500 individual angel investors invested $17.6 billion as part of 57,000 deals, 47 percent of which were in early stage ventures. By contrast in that same year, 794 institutional venture capital funds invested the same amount ($17.69 billion) as part of only 2,800 deals, only 9 percent of which were considered as investments in early stage companies.

Angel investors may invest individually, in small groups of two or three fellow investors, or as part of structured angel investor groups, whose number may range from 25 to 100. The metrics furnished by the Angel Capital Association regarding the profile of structured angel groups are instructive (*see www.angelcapitalassociation.org*). The prototypical angel group investor has been an angel investor for 9 years, has made an average of 10 angel investments during that time, have themselves founded 2.7 new ventures during a 14.5 year tenure as an entrepreneur, is 57 years of age, has earned a masters degree, and directs fully 10 percent of his/her net worth to angel investments as an asset class. Such members are themselves either current or former successful entrepreneurs, and they also place investment bets on early stage companies run by other entrepreneurs, since they are more familiar with the challenges and the opportunities within the early stage ventures which comprise this asset class.

Early stage investment in high-growth, technology-based ventures is critical to commercializing technological innovations, to promoting our Nation's competitiveness, and to robust job creation. For the 25 year period from 1980 to 2005, firms less than 5 years old accounted for all net job growth in the U.S. (Business Dynamics Statistics Briefing: "Jobs Created from Business Start-ups in the United States," Jan. 2009). A representative list of firms initially funded by angel investors include Google, PayPal, Starbucks, BestBuy, Amazon, Myspace.com, facebook, Costco.com, Yahoo!, Alcoa, and Cisco Systems.

From both perspectives (those of early-stage entrepreneurs, and the angel investors who back them), there are several areas where the Federal government can take positive action to increase and accelerate both new business creation and private funding thereof. Equally important, there are areas where the Federal Government's best policy would be to take no action at all and let private matters remain private.

I. Regulatory Arena (Food and Drug Administration)

In recent years, the Food and Drug Administration has gone through extended periods without formal, resolute leadership. Political considerations in the wake of high-profile drug safety incidents have left regulators at all levels hamstrung, afraid to make any decision whatsoever during the long drawn-out process of regulatory

review of new drug candidates, medical devices, and "combination" technologies. In such an environment, entrepreneurs lose years in their product development timelines and must spend additional capital in order to pursue preliminary, and ultimately final, approvals of the technologies they seek to bring to market. As a result, early stage investors increasingly altogether avoid making investments in areas with greatest technological promise, for the following reasons:

- With extended (and some would say indeterminate) development timelines, is it not possible to predict what the risk-adjusted return on investment (ROI) might be for a given technology.
- Investors believe that given the internal culture of the FDA, regulators are incented not to make approvals in any case (for fear they may get it wrong).
- With the "regulatory risk" so great, angel investors are incented to make investments in other equally promising sectors and technologies which are not required to pass through regulatory scrutiny at all (*e.g.,* wireless, social media, entertainment software, business process services, etc.). The chilling effect of regulatory delay and/or indecision is palpable from an investor standpoint.

Recommendations:

- Fill critical vacancies at the FDA as quickly as possible.
- Charge the FDA leadership to send clear, consistent policy signals as part of its regulatory pronouncements, so that both entrepreneurs and early stage investors will understand the FDA's expectations, requirements, preferences, timelines, etc., within specific biotechnological/medical sub-sectors; enhance the agency's communication function.
- Speed up regulatory review at all stages of the FDA application and regulatory process.
- Perform a cost-benefit analysis to compare societal benefits resulting from a "calculated risk" policy, vs. a "zero-defect" policy as pertains to new drug reviews and approvals. Common wisdom within the biotechnology and pharmaceutical industries is that there is no such thing as a "safe drug"; there are drugs whose safety profiles offer substantial benefits to the overwhelming majority of patients who understand and personally accept the risks of a particular drug, undertaken with the guidance of their physicians.

II. U.S. Patent and Trademark Office (USPTO)

Similar to characteristic delays resulting from FDA regulatory review, the U.S. Patent and Trademark Office (USPTO) is significantly backlogged in its patent application review and patent issuance processes. It is a common thread of discussion within the entrepreneurial community that the USPTO is facing up to a 3.5 year backlog in processing applications. This delay not only adds to a company's developmental timeline requirement, but increases the legal costs that must be born by early stage ventures. Entrepreneurs and the angel investors who back them require more timely information regarding whether a particular venture's technologies will receive patent protection; patents are often one of the few assets an early stage venture can acquire. Relatedly, an early stage venture is required to know whether it has "freedom to operate" within a particular intellectual property landscape (*i.e.,* a general analysis that it is not likely violating other patent-holders' rights). Entrepreneurs are often told by investors to "call me when you have received your patent allowance" from the USPTO; however, the entrepreneur is not able to keep the doors open until that time. Given the significant gating factor that the patent application process represents, entrepreneurial managers must make decisions regarding allocation of time, capital, technology, and skilled labor, often under total uncertainty. To the extent the time-frame of this uncertainty can be minimized, from a patent perspective, the more efficient and efficacious the venture creation economy will be.

Finally, U.S. ventures often perceive little value in filing patents in strategic foreign jurisdictions, since there is little guaranty that local enforcement mechanisms are available or effective. Consequently, entrepreneurs often forego pursuing patent filings in foreign jurisdictions with poor or questionable enforcement mechanisms. Intellectual property is thereby abandoned for purposes of commercialization within that foreign territory.

Recommendations:

- Consider implementing a USPTO policy of "expedited review" for those technologies in strategic sectors of the U.S. and international economies (*e.g.,* biotechnologies, wireless technologies, clean technologies, renewable energy, etc.).

- Significantly expedite the review process and approval of patent issuances, whether this might require re-allocating existing resources or increasing staff levels to handle workload, or outsourcing backlogged workflows to private vendors at key thresholds.
- Continue to push for reciprocity for and enforcement of intellectual property rights within foreign jurisdictions.
- Study potential changes to the U.S. patent regime, whereby U.S. patent rights might begin from the time of award, not from the time of filing or disclosure. This would "toll" the patent application period and allow companies to exploit the full potential 20 year life of a patent. It would also increase the economic value of the patent for the firm and from the perspective of early stage investors.

III. Federal Tax Policy

The 15 percent capital gains rate has been cited as one of the most important reasons for the increase in angel investment levels in the last six years. Any significant increase in capital gains rates will significantly curtail the number of investments made in this high-risk asset class. At a time when all other economic indicators point to less available capital for small business at the same time that the sheer number of potential investors has plummeted with the economic downturn, it would be counterproductive to increase capital gains taxes for individual investors who embrace great financial risk to directly support innovative, start-up companies.

Additionally, Federal ordinary income tax credits for angel investments in small business start-ups would also improve the flow of angel capital to small businesses in communities throughout the country. Twenty-plus states and several foreign countries have instituted income tax credits over the last decade. These credits are generally offsets against other investor tax liabilities and enhance the attractiveness of early stage, high-risk investments in early stage enterprises. A Federal tax credit could ensure that innovative small businesses would benefit from such investor credits, irrespective of state of domicile. A nationwide credit would enhance the benefits offered by states that already have such programs as offsets to state taxes (federal ordinary income tax obligations are greater than state tax liabilities). In addition, a tax credit with a nationwide footprint could help encourage more syndication among and between angel groups in different states, which is increasingly the manner by which entrepreneurs are able to raise larger rounds of financing. Several state-level precedents are instructive. A 2008 study of Wisconsin's angel tax credit program and related initiatives found that overall investment in Wisconsin small businesses increased by 43 percent from 2006 to 2007. Wisconsin-based angel groups increased their investments by 57 percent and more than doubled the number of small businesses that benefited from Wisconsin's policy initiatives during the same period.

Beyond the realm of angel investors, recently proposed legislation to tax "carried interest" earned by venture capital fund managers at ordinary income tax rates rather than at capital gains rates will significantly reduce the number of institutional venture capital funds being raised and consequently the amount of capital deployed to the most deserving entrepreneurs. In normal cyclical fashion, the venture capital industry expands by two-thirds during "boom" times, and then contracts by two-thirds during "bust" cycles. During bust cycles, venture capitalists "retreat upstream" and pursue later-stage companies whose risk/reward profile is lower than that of early stage companies. Thus, there is already a strong cyclical contraction underway; to reduce the compensation earned by venture capital fund managers will substantially exacerbate this already challenging trend. Venture capitalists will forego or abandon their involvement in the discrete asset class of venture capital, and instead pursue other areas within the investment professions, such as traditional mutual fund management, asset management, commodities and/or currency trading & arbitrage, where the risk/reward profile will appear more attractive. The "drying up" of early stage venture capital sends an extremely discouraging signal to early stage entrepreneurs (particularly within the biotechnology arena), and it has the very tangible effect of channeling both capital and managerial talent into other industries and technology sectors which require less total capital, over fewer years, and which do not include "regulatory risk" as part of their investment profile. Unfortunately, such industries are of less strategic importance to the Nation's competitive standing (*e.g.,* niche consumer products now receive investor capital vs. pharmaceutical development; entertainment media deals are funded vs. clean energy technologies).

Recommendations:

- Encourage Congress to keep capital gains tax rates for angel investments in truly early-stage businesses at 15 percent or less when it renews tax legislation for long-term capital gains this year.
- Given current economic conditions, Congress should consider complementing a lower capital gains rate for successful early-stage investments with a tax credit for investments in innovative small businesses. Federal ordinary income tax credits for individual angel investors in small business start-ups would also improve the flow of angel capital to small businesses in communities throughout the country. The Angel Capital Association could serve as a resource to advise legislators and policy makers on best practices gleaned from the twenty-plus states who have implemented state-level individual tax credit programs to promote growth of small businesses that create high-paying jobs.
- Resist calls for changing the taxation of carried interest for venture capital fund managers from capital gains to ordinary income. Such a policy would greatly reduce the already shrinking pool of available venture capital and result in a significant drop-off in new venture funds being raised.
- Beyond ordinary income tax credits for individuals, corporate tax credits for small firms could be linked to levels of outside capital investment attracted, employment gains made by small firms, capital equipment purchased, or some combination of these measures. There has been experimentation in this area at the state level as well. The effectiveness of this proposed policy however is admittedly lessened for those early stage technology-based firms which operate for several years without meaningful revenues (which is not uncommon).

IV. Federal and State Securities Regulations

Federal rules require individual investors who seek to invest in an early stage company to meet certain threshold requirements of either wealth or income level. As the economic downturn has decreased the number of individuals able to meet these thresholds, consideration should be given to lowering one or both the standards.

Additionally, the Federal Government should continue its beneficial policy of permitting the exemption of early stage company stock from the usual securities and exchange listing requirements under Regulation D of the 1934 Act. This exemption saves early stage companies and their investors significant time and money, which are at a premium for such enterprises.

Recommendations:

- Preserve, and potentially lower, the traditional definition of "accredited investor(s)" for securities and tax law purposes. Conversely, raising the threshold definitions will vastly reduce the number of angel investors eligible to make investments in early stage companies.
- Continue to protect the "Reg. D" exemption under the '34 Act for the offering of stock in early stage ventures.
- Study the potential benefits of simplifying the complex patchwork of all Federal regulations within the area of securities issuance exemptions.
- Pursue harmonization of Federal laws with the patchwork landscape of the states' own "Blue Sky" securities regulations. This would provide regulatory and financial relief to early stage firms, which often must incur onerous legal cost to ensure compliance in numerous state jurisdictions.

V. Programs Promoting the Development and Integration of Local/Regional Infrastructure and Critical Resources for the "Entrepreneurial Ecosystem"

Two programs showing early promise and worthy of promotion at the Federal level are as follows:

A. The Florida Institute for the Commercialization of Public Research (FICPR)

The Florida Institute for the Commercialization of Public Research (FICPR) matches commercially-viable technologies originating from the states' public and select private research institutions with: (i) experienced start-up managers (entrepreneurs) and (ii) private investor capital (angel investors, venture capitalists, and corporate development partners). FICPR is an unprecedented collaborative effort of the technology licensing and commercialization offices of Florida's eleven state universities as well as those private research institutions within the state that receive public funding. These partners are the gatekeepers charged with licensing technologies to startups for commercial product development leading to company growth and job creation. A nonprofit organization formed by the Florida Legislature in 2007, FICPR's mission is to create new, innovation-based companies and jobs by

supporting entrepreneurship and commercialization of publicly-funded research in the life sciences, aviation/aerospace, clean energy, homeland security, and information technology sectors.

In addition to the aforementioned "matchmaking function," FICPR expands access to early stage capital by administering Florida's newly authorized Commercialization Matching Grant Program, which provides matching state funds to qualified Phase I and Phase II SBIR Federal grant and STTR Federal grant awardees. The multiplier effect of this program significantly expands the initial award of Federal grant monies with new sources of both state funding and private investor capital.

Finally, FICPR expands and strengthens the connectivity among the state's technology business incubators, local innovation networks, prototyping facilities, strategic workforce training agencies, angel investor groups, and other entities through which additional training, communication, financing, and relevant support services are provided to early stage ventures. In this role, FICPR leverages existing assets and infrastructure, connecting the dots in a state often characterized by regional and institutional insularity.

In the near future, FICPR aspires to foster even greater connectivity among the many separate elements of the entrepreneurial ecosystem by leveraging requested Federal funding with other state and locally-funded initiatives and programs. The collaborative model implemented by FICPR represents a successful precedent that is worthy of study and replication, both regionally and nationally.

B. Promote the Establishment and Growth of Private Angel Investor Groups and Networks

Since angel investors have most recently accounted for roughly half of all early-stage funding last year (also consistent with the long-term trend), entrepreneurs and the early stage businesses they start would benefit from an expansion of organized angel investor activity. One challenge facing policymakers is that angel investing is, by its very nature, an inherently private sector matter. Providing private investors with exposure to best practices and a roadmap for how they may organize collaborative angel investment activity at local and regional levels is perhaps the best manner of promoting private investment activity in early stage companies. The Angel Capital Education Foundation (ACEF), a national source of education and research on angel investing, serves as a resource and repository available to assist private investors, entrepreneurs, support organizations, legislators, and policymakers who seek to understand, pursue, access, and/or promote angel investment activity (*www.angelcapitaleducation.org*).

Recommendations:

- Federal agency heads and Federal legislators should become familiar with the programmatic successes of both the Florida Institute for the Commercialization of Public Research (FICPR) and the Angel Capital Educational Foundation (ACEF). Where possible, the programs and initiatives developed by both entities should be supported, replicated, extended, and also integrated into existing Federal programs (as relevant).
- Specific consideration should be given to funding the FICPR's upcoming grant application to the i6 Challenge Grant program (sponsored by the U.S. Department of Commerce's Economic Development Administration, in partnership with the National Institutes of Health (NIH) and the National Science Foundation (NSF).

VI. SBIR and STTR Programs.

The Federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs have been a staple of early stage company formation and advancement for many years. While the time and scope of this testimony do not permit a sufficient overview of each program, the core takeaways are as follows:

- SBIR and STTR grants provide key financing for early stage companies seeking to bridge the "Valley of Death" between initial seed capital (most often provided by entrepreneurs themselves, their "friends and family," and/or angel investors), and later, larger financing rounds from institutional investors (*e.g.,* venture capital funds and large pharmaceutical firms).
- SBIR/STTR grants serve an important "validating" function for later investors, signaling that the science supporting the technology under development by an early stage firm has gone through peer-review during the grant award selection process.

- SBIR/STTR grants are often the sole source of funding for "highest risk/highest reward" projects which seek to demonstrate the first "proof of concept" for a given technology.

In recent years, funding for the SBIR and STTR programs has been threatened by larger corporate and institutional investor interests, who would prefer to see Federal funding steered toward later-stage, larger enterprises. However, SBIR and STTR grants, primarily intended for small and mid-size enterprises, are literally the "seed corn" for much of this Nation's most innovative private research and development efforts.

Recommendations:

- Preserve Federal funding support for both the SBIR and STTR programs.
- Protect SBIR and STTR programs from encroachment by larger firms which seek to displace earlier stage firms from grant award funding, potentially by imposing ceilings on the size of enterprise that may be eligible for grant funding.

VII. Conclusion

Again, I would like to thank Senator George LeMieux (R.—Florida) for the opportunity to share these observations and recommendations with the Honorable Members of this Senate Subcommittee. Federal policies supporting: (i) entrepreneurs, (ii) the early stage ventures they launch and grow, and (iii) the early stage investors who back them, all contribute to an ecosystem that is part of a virtuous cycle of high-wage job creation, increased tax revenue (over the long-term), dynamic innovation, and robust competitiveness on the global stage. By the same token, as suggested earlier, restraint at the Federal level is often the best available policy option.

Senator KLOBUCHAR. Well, I'm sure Senator LeMieux won't let you go without some questions.

I, first, turn to you, Dr. Atkinson. Both Senator LeMieux and I were interested—and I know Senator Warner and Begich have raised this, as well—this idea of a competitiveness policy. And I thought Mr. Chopra's analogy, with the broadband policy, which actually had some meat on the bones when it was put out there—how would you like this to look? Like, what would it really be, this competitive policy?

Dr. ATKINSON. Well, I think—it's interesting, in my written testimony, I allude to how many other countries have done this. Ghana just recently established a process to do this. So, many countries are doing this. And it involves more than just simply several people getting together in an interagency process every few weeks and drafting up, you know, a little white paper, as helpful as that may be.

I think what it requires is a very serious analytical effort. And one of the things the broadband team did is, they brought in people from groups like McKinsey and Boston Consulting Group—real experts, real—people who do this for a living—brought them in on detail, and spent 9 months going deep into what the real challenges are. So, I think we need to do that. We need to, for example, look at the medical device industry, look at the IT industry, look at aeronautics, a whole set of things: Where are we strong, where are we weak? What are the challenges they face? Then look at a whole set of things around what you call "support factors." How is our regulatory system working? How is our tax system, compared to other countries? How are we doing on public investment and policies to spur technology transfer and commercialization? What can we learn from other countries? And then develop a whole list of recommendations that both the Administration and Congress could follow up on.

Senator KLOBUCHAR. Has anything been done like this before?

Dr. ATKINSON. We've done two things like this before in this space. One was President Carter's 1978—I believe it was 1978—Domestic Policy Review on Innovation. And this was a very serious, long-term, you know, 8 to÷ months kind of effort, looked across the board. And this actually stimulated a lot of the follow-on activities in the 1980s—the Bayh-Dole Act, the Collaborative Research and Development Act, a whole set of other things.

And then again, in 1983 or 1984, President Reagan established the Industrial Competitiveness Commission, and that also did a lot of analysis and led to a whole set of other acts, including helping shape the Omnibus Trade and Competitiveness Act of 1989.

So, we have done these things before. And we did them, I think, pointedly, when we thought we faced real challenges with the Japanese and Europe, challenges in the 1970s and 1980s. And then we sort of decided we didn't need to do this anymore, and put it aside.

Senator KLOBUCHAR. And I can look into this more, myself, but do people point to it, then, sometimes? I feel, sometimes, that people are just responding to various groups that are coming in all the time—auto industry, this industry. And it does seem to me that it would be incredibly helpful to—even hearing Fred Hochberg, the head of the Export-Import Bank, list some of our top export potential, and look at what those are, and look at, How are we helping them? How are we hurting them? And then, also, as you point out, bigger policies that would help everyone so we could——

Dr. ATKINSON. Could I make a——

Senator KLOBUCHAR.—use it as a guidepost?

Dr. ATKINSON. Could I just make——

Senator KLOBUCHAR. Go ahead.

Dr. ATKINSON.—one other point?

I think an interesting point—I—when I was Chief Advisor to the Governor of Rhode Island, back in the 1990s, for the Economic Policy Council there, we actually put in place a very detailed strategy. We looked at nine key industries in the state. We understood their competitive position. We then looked at all these crosscutting things. We put in place a policy that led to a whole—a plan and a strategy that led to a whole set of policies. But, we weren't the only state that has done this. I believe Minnesota has done this. Many states have put in place competitiveness strategies. And it's just striking that somehow states can do this, but we don't think the Federal Government should.

Senator KLOBUCHAR. Well, especially when we're competing in a global economy.

You also mentioned OIRA, this whole idea—did I say that right? It's Cass Sunstein's position.

Dr. ATKINSON. Right.

Senator KLOBUCHAR. And he was my law professor, and my law review comment advisor, so I know him well and have a lot of respect for him, including the work he's doing with the book, "Nudge," and all of the other things he's done. Do you think that—you mentioned it—could they play a bigger role in this, as we look at how we deal, in a positive way, with the FDA, to move them and work with them to see, not just one side, but also understand this innovation side, that there are ways you can ensure safety, but do this in a way that doesn't discourage good investment?

Dr. ATKINSON. Yes. This was a proposal that we actually made from work that two of our colleagues did—Arti Rai and Stuart Benjamin, who were both law professors at Duke University, and proposed this idea and had it as a law review journal and then an ITIF report. Both of them are in the administration now. Stuart is at FCC, and Arti Rai is at the Patent Office. And obviously they're big proponents of this idea. And the point that they make in their report in—is that OIRA, right now, is basically a cost-benefit agency, so it looks at what agencies are doing from a very narrow perspective—what economists would call "static analysis." How is this going to affect just what's going on today? There's very little capability or focus on how this might affect things, 5 years down the line or 10 years down the line. How do what agencies do and how do—what they perform—how do they——

Senator KLOBUCHAR. When you listened to Mr. Weiss, it's 10 years for one product. But, go on, yes.

Dr. ATKINSON. Well, you're—it's just this—there's nobody in—at OMB standing over the shoulder of agencies, looking not just at the rules that they propose, but their operations, and saying, "You know what, you're not structured to support innovation as well as you could."

So, our view is, a very small effort in OMB—it doesn't need to be a lot of money, but just someplace in the Federal Government where that's what they're doing every day, and really urging agencies to take innovation more seriously.

Senator KLOBUCHAR. Very good.

Mr. Ubl, you mentioned something—and maybe it was in your written testimony, but maybe we just talked about it before—that China is looking at this country-of-origin policy, in terms of when they allow products in, that you have to have an OK in your own country of origin. Well, it's pretty easy to put the dots together. But, if it's taking us years longer than it is, say, France or England, or just Europe as a whole, to OK a product, if you're a businessman or -woman, and you want to get something in China, what motivation is there to stay here, if our policies take too long?

Mr. Ubl?

Mr. UBL. I think that's a terrific point. I mean, if you picture two gateways, the FDA review process, which is, at best right now, unclear, and could potentially get more arduous for companies, and you look at the European CE Marking process, under which many medical technologies are on the market for several years before they're available to U.S. patients, the choice is pretty clear, that you're going to continue to pursue the more efficient path.

And, as I mentioned, our concern is that that is going to be the beachhead under which, if China and India are the target markets, the whole industry is going over time to migrate abroad not only manufacturing, but clinical trials, R&D, the whole value chain.

Senator KLOBUCHAR. Does China actually have that policy in place right now?

Mr. UBL. They do.

Senator KLOBUCHAR. OK.

We all know that there are advantages of the U.S. I mean, I don't think we have to go into it. You know that. You represent the companies, with our long history here, and the people who are

trained, and the well-thought- of products. But, as Dr. Atkinson said, looking 5 years down the line here, if we don't respond to this quickly—because we live in a global world, and it's going to make a difference.

Could I—just one more question—I know there's an Institute of Medicine study coming out, on this 510(k) process. Do you have any information about the study? Have they included all interested parties in working on this study?

Mr. UBL. The IOM has just recently begun its inquiry into the 510(k) process, and they will report, Spring or Summer of next year.

We do have some concerns that the IOM Review Committee does not include a great number of people who have actually developed products, and brought them through the commercialization process, although they are opening their process to outside comment.

I think, to understand the value of the 510(k) process, you really have to appreciate the innovation model in medical technology. I sort of liken the drug discovery model to the Big Bang theory, where you test a compound for a number of years, you find one that works, the compound doesn't change, going forward. Medical technology, by contrast, is like the software industry; it's rapid, incremental improvement, where you have new products coming out every 18 to 24 months. And the way those incremental improvements are brought through the regulatory process is through the 510(k) process, which allows you to make these modest incremental improvements that, when you add them up, make a powerful impact on public health.

So, it's the main superhighway, if you will, where most medical technologies are brought through the process.

Senator KLOBUCHAR. And the concerns that I've heard is that, you know, suddenly there has been—it's not that you couldn't perfect the process and make it better and make some changes, but there's—it's sort of sporadically happening right now, without a lot of lead time, so that companies and investors can adjust to that, so that you—instead of saying, "This is how we're going to change it in 3 years," suddenly, on the 89th day of a 90-day process, someone's suddenly asking for a $40-million new study, is what I'm hearing. Could you comment on that?

Mr. UBL. I'm hearing a lot of that, as well. On the one hand, there's a great fear of the unknown, where the agency is looking at the process, and the IOM is looking at the process, investors and companies don't know what's going to come out of the other end. But, yes, an analogy I would use is, today it's built like the "Peanuts Cartoon," where you've got Charlie Brown trying to kick the field goal, and Lucy, at the very last minute, pulls it away. Many companies are very frustrated that they'll go and make an agreement with the agency over the data that's required, only to have a new reviewer put in place, or new data requirements being requested. And that just throws the entire process up in the air.

Senator KLOBUCHAR. Mr. Weiss, do you want to comment a bit more on this, in terms of the questions I was asking Mr. Ubl? And how could we change this? While still understanding that you can always make a better regulatory process, and there are probably some changes that safety experts, consumer advocates, patients

groups, as well as medical device industry would support—how do we do it in a way that makes it work, so you don't unnecessarily limit investment and send it all over to Europe?

Mr. WEISS. Well, I think Mr. Ubl put his finger right on the issue. The fear of the unknown makes it very, very difficult for companies like ours to plan. When we can't put a plan together, then, fundamentally, we can't attract investment. So, investors are looking at medical devices with more uncertainty that they had before.

So, the first thing to do is to take uncertainty out of the process. There's a number of ways to do that. One is to assure that companies that are in the process today are grandfathered to whatever the current system is. The second one is to involve industry in the development of the new processes.

And what seems to have happened in the last few months—and now, with the review process, led by Dr. Shuren—is that there seems to be signaling by the FDA that they're going to change something. And, whereas we have the right to provide comment, the—there are a lot of questions as to whether or not that's real input, and whether we can help shape the process.

That's why we—you know, we're so grateful for the opportunity to speak here today, to see what kind of support congressional support and visibility can provide.

Last, I think that the basic principle of harmonization with the European system would be advantageous to everyone. These same issues are dealt with in Europe with stratified risk, risk-reward benefits, the different levels of risk that devices have. And I think harmonization with the European system is a positive idea.

Senator KLOBUCHAR. Very good, thank you.

Mr. LeMieux has returned.

Senator LEMIEUX. Thank you, Madam Chair.

I wanted to, if I may, ask a question to you, Mr. Williams. Something that you and I have talked about—in fact, we talked about today, and it was mentioned earlier, and Senator Warner and I were discussing it—is this Valley of Death challenge. And maybe other folks on the panel will also speak to it.

Where we do a pretty good job in helping folks, in getting investment to people when they're working in their garage, or they're at a university and they're working in the lab, we do very well once a product has been developed, sort of the end of the spectrum, getting investment to folks. But, that middle time seems to be a very challenging time for these folks to get the money so they can continue developing their product and getting it toward commercialization.

What can the government do, and what models might there be out there that other States have tried successfully, that can help bridge that gap so that we can bring more of these good ideas to marketplace?

Mr. WILLIAMS. One idea comes to mind. And I've heard that there may be three different proposals floating out there now for a Federal angel investor tax credit. Fully 20 States and some—three foreign jurisdictions—have already tried experiments in this area. I know the State of Wisconsin is a standout success in this area. In a 2-year period, where they used a State angel investor tax

credit, combined with their other policies, they—there was a 57-percent increase in the amount of funding given to small businesses. And I think an increase in the absolute number of businesses receiving funding jumped by 47 percent. An Angel Capital Association report, dated April 16 of this year, indicated that there were three proposals somewhere out there. And—I think, in the House. But, that's something—I think, it's definitely—I believe the Federal Government could look at those examples and maybe call for best practices, and see which policies might make the most sense.

Additionally, right now, the ecosystem is significantly disrupted with the contraction of the venture capital industry. Angels used to be able to take big, broad bets on the big ideas, the big technologies—clean tech, pharmaceutical therapeutics—and then trust that the better ones would survive, perhaps then with Federal grant funding, and then be picked up by the venture capital industry. That's no longer the case. The venture capital industry has contracted. They're feeding their own young. Their existing portfolio companies. They're not making new bets.

And so, there's a Valley of Death within the Valley of Death. And so, I think we really need to—as I said during my primary comments, we really need to support the venture capital industry, and look at specific comments, in tax policy and other realms, to help establish it. It really is our—the pride of our country. It's the envy of the world. And we need to do what we can, I think, to foment additional, you know, robust recovery of that industry.

And I'm kind of surprised to hear an angel wax so positively about VCs, because frequently we are somewhat competitive across the negotiating table. But, there is a very important ecosystem there. So, I think that's very important.

Senator LEMIEUX. Mr. Weiss, do you want to tackle that?

Mr. WEISS. Yes, I appreciate the opportunity.

And I—and let me just reinforce what was just said. I advise a number of very early-stage companies, and I also work with a number of venture capitalists. There are a number venture capital firms that have simply withdrawn from medical device investing. They view that the uncertainty in the regulatory environment, the complexity and challenges of getting insurance coverage and reimbursement, and the—just simply the time to get a trial done, as untenable. So, they can't attract investment into their funds.

And the—exactly the issues with angels are compound by this sort of, you could say, the second Valley of Death. I know half a dozen venture funds that have either moved to much later-stage or just completely withdrawn from startup venture investing. And the impact of that, unfortunately, is—I've spoken to a number of companies that I've advised, "It's very, very difficult for you to get any funding at all, so don't even start." And it's really become a bigger and bigger problem.

And in the Twin Cities, a number of venture-backed companies have simply shut down, because as venture funds have contracted, they have had to pick and choose which of their companies they continue to fund. And there are two or three, just in our building, that have left recently.

Senator LEMIEUX. Mr. Ubl?

Mr. UBL. Just briefly. I was in Israel last week, and I was struck by two things. One is, they do have a comprehensive innovation policy, of which medical technology is a key pillar. The second thing I was struck by is that the government has some fairly novel approaches to trying to cross the Valley of Death. For example, if small companies are able to secure private funding, the government will match that funding through the life cycle of the technology.

So, I think that, if we can look at some novel ways of strengthening the seed-funding aspect of this, and creating incentives throughout the development process, that would be one suggestion I would make.

Senator LEMIEUX. Dr. Atkinson?

Dr. ATKINSON. My colleagues talked more on the venture side or the angel side; let me talk about even prior to that. The first step to even get into the Valley of Death is to get something to take research and put it into a prototype or a business plan. And we do that well in some places, but in a lot of places, we don't. I would look, for example, to MIT, where MIT has a whole ecosystem, where, if you're a faculty, or even a student, with a good idea, you can get what are called these $50,000 ignition grants. It's not a lot of money, but enough money for a faculty member or a student to develop a plan, to go out and start to talk to venture capitalists or angel investors. We need to have all our universities doing things like that.

The second thing related to that is, there are States now that have very good public/private partnerships that work to get technologies out of universities and to provide, sort of, early-stage management help, sometimes with incubators, so they can—and States, including Florida, Minnesota—a lot of States have programs like that. Frankly, they're significantly underfunded.

So, I think we need to think about—was that proposal that I made in my written testimony, of what we call the SCNR, sort of like an SBIR, but—again, taking a small amount of money, and really spurring these kinds of efforts.

Related to this is what other countries are beginning to do is actually tie university funding to their ability to commercialize technology. In Finland, for example, 25 percent of their higher-ed budget now is tied to performance. In Sweden—they just started this last year—10 percent of their higher-ed budget is tied to performance, with about half of that performance metric being, Are you commercializing technologies? Are you working with entrepreneurs? Are you, sort of, getting out of your comfort zone?

We don't do anything like that here. We could start to take very small steps in that direction, to begin to provide incentives for real performance.

Senator LEMIEUX. Mr. Weiss, did you have another comment?

Mr. WEISS. No, thank you.

Senator LEMIEUX. OK.

Senator?

Senator KLOBUCHAR. OK.

Well, I wanted to thank all of you. This has really been a very good hearing.

Maybe Senator LeMieux has a few closing remarks, as well.

What I'll take away from this is, first of all, this—several of Dr. Atkinson's ideas, and that were, I'd say, echoed by Mr. Chopra, in terms of a competitiveness strategy for our country. I think all of us share some frustration with the regulatory system. We've certainly heard that from our very successful medical device industry, and one that we want to keep successful, as well as across the board with other innovative businesses. And that's something we need to work on. And I am very committed to doing that.

The patent issues that we talked about, and then, overall, the need to focus on exports. I think you saw common ground here, across party lines.

And if I left you with anything, it's what I'd leave with Mr. Chopra, is that we have to act, here. We are competing in a world against some incredibly vigorous competitors that aren't going on listening tours. We need to do something, and get it done now, in terms of making a better environment for innovation in this country. And I know those of us up here on this subcommittee are committed to doing that.

Thank you very much.

You want to add anything——

Senator LEMIEUX. I do.

Senator KLOBUCHAR.—Senator LeMieux?

Senator LEMIEUX. I want to, first of all, thank Senator Klobuchar for her leadership on this, as well as the leadership on exports. These are such important issues for medium and small businesses across the country.

And I want to thank you all for the work that you've done and the testimony that you've given today. This is not a partisan issue; this is about the competitiveness of this country. And I think we identified, today, the components of what this innovation plan needs to be focused on. It needs to be focused on making sure that regulation is efficient and effective in getting rid of the lag time, whether it's at the FDA or the Patent Office. We need to make sure that the tax environment is of the sort that's going to promote innovation. We've got a focus on increasing exports, as well as a focus on providing funding, where appropriate, to allow these companies to be able to develop their ideas and bring them to the marketplace.

So, you've given us a lot of great information, and we will be back in touch with you, because I think this is something that Senator Klobuchar and I are going to work on together.

Senator KLOBUCHAR. Very good.

And, Senator LeMieux, I'm off to talk to some of our people in Tourism—I think that's sort of important to Florida, isn't it?

Senator LEMIEUX. Slightly, yes.

Senator KLOBUCHAR. Yes. Which is another part of our subcommittee.

So, thank you very much, everyone. And we look forward to working with you in the future.

Thank you.

[Whereupon, at 4:30 p.m., the hearing was adjourned.]

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