Submitted in Response to RFI: Building A 21st Century Bioeconomy (OSTP)
Jonathan Kuniholm (Capt (Ret) USMC-R), President, Open Prosthetics Project
[redacted]

Grand Challenge: Deliver A Bionic Arm for Veteran Amputees
Bionic arms are not yet here. We've spent hundreds of millions of dollars on prosthetic arm research since the spike of arm amputation injuries in our wars, but *not one single new prosthetic arm device or component has been introduced to market as a result.* It's time to keep the promises that we have made to our veterans.

We need grand challenge to deliver a real bionic arm. Because this can't happen in a single step, the challenge will consist of an annual list of tasks on which entries will be evaluated, and we will continue the challenge until we have succeeded. All tasks must be performed under amputee control, the arms worn by real amputees of various levels, and the arms completely self-contained. The final challenge will be a competition against a human arm.

The challenge will be modeled after the DARPA Grand Challenges with important exceptions. Using the values of "cooperatition" and "gracious professionalism" championed by the FIRST Robotics League, the challenge will be based on and will encourage the shared development of the electromechanical and software tools necessary to participate in the challenge, and collaboration among the participants will be encouraged (but not required) through the structure of the challenge, and through the use of this shared platform.

Policy Recommendations for "Orphan Device" Innovation

- **Common platform and "app store" for encouraging collaboration**
- **Private corporation "The Stumpworx," owned by disabled vets to commercialize and shape priorities**
- **SDVOSB set-asides for consumer businesses that serve owner interest**
- **Coordination or at least transparency in single-topic government funding**
- **SBIR/STTR programs designed to work with overall strategy**
- **Voluntary industry standards for interoperability and interconnection with support to non-profits to maintain them**
- **FDA policy that encourages development of new orphan devices**
- **Eliminate the FDA's "Class III Cootie" problem with modular systems**
- **CMS (Medicare) reimbursement as an incentive for innovation**
- **Exercise government license or Bayh-Dole "march-in" in failure to perform**
- **Funding for student projects and programs at all technical levels that serve orphan device communities and encourage contribution to the commons (workforce)**
- **Use "Vehicle Forge" collaboration platform for development**
- **Better information about funding opportunities that allows outside web 2.0 markup and organization**

An Arm Development Platform to Build From—An App Store for an Android-like Ecosystem
Recent investigations into replacing arms with bionics and prosthetics show promise, but the challenge is huge, and we've only begun. In order to leverage the technology we've already developed, we need a common platform for further electromechanical and software development. This will help lower the marginal cost of innovation, and increase its pace. By taking the greatest advantage of research to date, we can ensure going forward that research initiated by the government builds on what has already been achieved, rather than duplicating it, or falling short. Anyone who wants to go it alone is welcome.

Initially, we hope to support the creation of the platform through a voluntary research consortium consisting of a **public-private partnership** of technology stakeholders from the DARPA Revolutionizing Prosthetics Project, non-profit and consumer advocacy groups, private

companies, government-funded academics, and their funding agencies. Through the structure of the research platform hardware and software, which will be created in the mold of the Android smartphone ecosystem, participants can develop incremental or revolutionary improvements at any level that they choose. The use of common software and hardware protocols will allow the creation of hardware peripherals and software "apps" that allow the participants to mix and match the best of their efforts to solve common goals. As smartphone ecosystems have encouraged rapid and explosive innovation, so too I hope that this platform can not only make the most of existing and future government research expenditure, but also make it easier for private investment to have an impact in this underserved area.

The creation of this common research and development platform will serve as a model for innovation not just in prosthetics and robotics, but also in the service of other disabilities similarly underserved by our health system— what can be called "Orphan Devices." This common platform will center the larger public-private partnership that must be created to bridge the so-called "valley of death" that separates research from real products. By bridging the divides of communication and collaboration among the players—government, academia and industry—who have failed to solve these problems on their own, we can also bridge the valley of death that has separated them from results.

DARPA's "Vehicle Forge" platform currently under development could be a model for integrating innovation from a combination of government and private sources.

Crossing the Valley of Death—Getting *Orphan Devices* to Market
While this is a commonly acknowledged problem, it is not one that anyone has convincingly addressed. As discussed above, government research hasn't produced any new devices that patients have access to. This is a source of embarrassment and frustration for all of us who have worked hard on these programs, as well as for all of us who are waiting for a solution as patients.

The problem is, in general, not a technical one or a regulatory one, but an economic one. There are simply not enough arm amputees in America or the rest of the world with the health care resources to warrant private investment in solving the problem. In parallel with orphan drug populations numbering fewer than 250,000 patients, the 41,000 arm amputees in America require an even more challenging remedy—the orphan device.

No venture funding is going to target a market in which investment is unlikely to be recovered at all, much less yield a seven-fold or larger return. The problem consists of a multiple market failure that has been solved neither through government funding and academic research, nor by the private sector. Any potential solution must involve the better coordination of each of these sectors, through creative approaches, to take advantage of the strengths of each one.

This is a challenge that we must overcome as a society, and it is by no means unique to prosthetic arms. Of the more than 6,000 orphan conditions listed by NIH, missing an arm is not one of them. This document mentions multiple strategies, based on responses to the RFI, which might be used to successfully attack this problem.

Stumpworkx: A Service-Disabled Veteran Owned Small Business as Part of the Solution
No one is more personally invested in finding a solution to the problem of missing an arm (or any medical condition) than someone who suffers from the problem. I have begun the development of a venture owned not just by a single veteran arm amputee, but by ALL of them. By early 2012, Stumpworx will be incorporated. This venture will be part owned, according to its bylaws, by every service-connected arm amputee rated for disability by the DoD or the VA for the amputation of at least a hand. Through what I call a private-sector entitlement, veterans who have lost their arms in the service of their country will have a seat at the table in deciding what products we as a company develop on our own behalf. Shareholder meetings will likely end up being some of the best market research the industry has ever seen.

This company has been conceived based on the premise that it is possible to best serve patients in this orphan device market not by protecting good ideas as intellectual property, but by sharing our ideas and inviting others to help us solve this difficult problem. I am starting this business because the private sector has not stepped in to commercialize any of the next-generation technology developed by the government for prosthetic arms over the last decade. Most tragically, and in stark contrast to what happened after World War II, neither industry nor government has stepped in to improve any of the previous generations of technology. I wear a hook that still bears the name of the man who patented it in 1912, despite two corporate acquisitions since 1960. Though I have shared several ideas for more incrementally improved prosthetic components, such as a body-powered harness, these things have gone unnoticed and unexploited by the prosthetic industry. This venture is an acknowledgement that sometimes, you have to do things yourself if you want them done (the lesser-known seventh troop-leading step, BAMCIS-**D**).

I hope that Stumpworx will be able to work closely with the government agencies that fund prosthetic research, and the recipients of funding, to improve both the quality and focus of this funding, as well as the sector's track record for successful commercialization.

The Open Prosthetics Project—More User Feedback and Involvement
A 501(c)3 non-profit, the Open Prosthetics Project is an online community consisting of a collection of low-cost websites dedicated to the sharing of ideas about prosthetic design, and as a patient community for discussing all of the issues surrounding our common physical challenges. The project includes a number of initiatives that will be expanded and supported by Stumpworx, in much the same way that Google, IBM, Red Hat and Buglabs work with the open source communities they support and benefit from.

The Open Prosthetics Project (OPP) appears in the first page of Google results for "prosthetics," which I think says more about the poor quality of information available to amputees online than it does about the quality of what we provide. That said, I think that we have accomplished quite a bit without any resources, and compare favorably with The National Resource Directory (http://nationalresourcedirectory.gov/), Disability.gov, www.prosthetics.va.gov, or any number of much better funded websites.

We have a number of ideas for the expansion of the features offered by the website, and it is our hope to interest others in the shared development of these features and the expansion of similar sites serving many communities of this kind. One such idea could be government-funded tools that would help websites like mine interface with government funding data and other resources.

Industry Standards for Interoperability
OPP has been proposed as a shepherd organization for a couple of open standards that are being developed in the prosthetic industry, a mechanical wrist connection standard and an electrical communication bus standard (see attached letters of support from industry for this standards initiative).

Regulatory Barriers
FDA regulation of prosthetic arms is absolutely NOT a barrier to the introduction of new prosthetic arm components as they exist and as the FDA currently interprets these regulations. Over the past few years, multiple new articulated hand devices have been introduced as Class I (Exempt) devices, exempt from both 510(k) Premarket AS WELL as the most basic Good Manufacturing Practices (GMP) and Quality Controls (QC) required of other Class I devices. This includes the most advanced myoelectric hands, hooks, wrists and elbows.

Unfortunately, the FDA has threatened to regulate similar devices as other than Class I (Exempt). Indeed, both DARPA Revolutionizing Prosthetics programs (2007 and 2009) have made inquiries to the FDA about the possible future classification of their devices. The answers have not been made public, and the message on this topic from the FDA has been both inconsistent and

confusing. I have called multiple officials at FDA, and have been unable to get a straight answer about the way that articulated electromechanical hands and arms are to be regulated in the future. This is at least in part due to FDA's historical role serving companies and regulating individual products, with absolutely no transparency regarding applications and records. Even as multiple highly articulated hands are introduced into the US as Class I (Exempt) devices, *the threat of more stringent FDA regulation* looms as a specter discouraging action and investment by others. Note that nearly identical devices are sometimes classified differently—Otto Bock Myo Boy (Class I Exempt) and Motion Control Myolab (Class II)—and even the manufacturers cannot tell you why this might be. I asked both, and both said it made no sense.

The FDA's Innovation Pathway
The DARPA Revolutionizing Prosthetics 2009 (RP 2009) Arm, developed by Johns Hopkins Applied Physics Lab and collaborators, was recently chosen as the FDA's model system for an accelerated approval process. While failing to acknowledge FDA's current treatment of similar Class I (Exempt) devices (similar excepting the neural interface, which is far from ready for human amputee use), the FDA has pressed forward and appears poised to classify all of the modular electromechanical components of the arm as part of an invasive Class III system, and the similar electromechanical components of the RP2007 arm as Class II. While the FDA may not currently be the real barrier to the introduction of these devices to market, this "streamlining" initiative, in addition to their responses on related devices, has the potential to *become* the reason.

An Alternative Pathway—Orphan Device Regulation as an Incentive to Innovate
Despite the fact that no commercial partner has been identified for the RP 2009 Arm, the entire system was announced as the model device for the Innovation Pathway. At the public announcement of this initiative, there was a lot of public griping by major medical device companies because their pet devices were not to be included in this initial program to fast track approval. I suggest that this is an opportunity for the FDA to take leadership, and rather than trying to use the prosthetic arm as a model for fast-tracking a device that assumes a commercial impetus to do it (with no commercial partner in sight anyway), instead creating a program that *incents development in orphan devices*. In contrast to dealing with complaints of "why wasn't my cardiac device fast tracked," the FDA could instead field requests to help with the development or production of the prosthetic arm or other orphan device.

FDA could in fact work in conjunction with the Centers for Medicare & Medicaid Services (CMS) to try and incent innovation with the promise to reimburse for certain capabilities or achievements, paying only for clinical results, without necessarily having to fund the development (see below for further discussion).

An important note on orphan devices: The orphan drug law creates incentives for pharma to produce these drugs by extending exclusivity. In prosthetic arms, the existing exclusivity available to patent holders is not being taken advantage of. Prosthetic arm patents, because of the small patient population, are routinely abandoned and maintenance is left unpaid after 7 or 15 years. At least for arm devices, extending exclusivity is not a viable solution.

Focusing Priorities in Research and Technology Development
The traditional model for moving technology from the lab to the market is for the university or professor involved in the research to license the technology for a fee to someone who seeks to spend additional funds (sometimes 90 per cent of the total R&D cost) to bring a product to market. For orphan devices there is no such incentive. Further, the university and professor share the desire to continue to perform funded academic research, rather than be involved in the details of commercialization. Government lab work is no different when focused on underserved areas—the lab's interest is usually driven by the research rather than the commercial interest. The focus on neural devices in prosthetic research, for example, ignores myoelectric pattern recognition technology, which was pioneered in the lab decades ago, and the few patents were abandoned or have expired. Commercial devices were never developed.

Government Funding for Prosthetic Arms Not Coordinated and Not Transparent
There are at least eight government agencies that have funded prosthetic arm research. These programs are often duplicative, almost never coordinated, and specific performers tend to be favorites of certain funders. Announcements of funding are generally available by source and not by topic, so even the portfolio managers at given agencies are unaware except by personal connection of what their counterparts are up to. Research.gov and grants.gov offer a limited picture and have bad search tools. Making the data available in a common platform across agencies so that outside groups (Google, or Open Prosthetics, *e.g.*) could organize the content in meaningful ways (socially) would be a much better alternative. See initiatives like Mendeley, Zotero, etc.

A new model that encourages researchers to use technology for research that can simultaneously be developed into medical device products by a company devoted to serving both labs and patients is a potential answer. By initially serving labs, and providing them with devices more capable and reliable than their students or researchers can produce on a prototype basis, such a company can transform these devices from prototypes around which many engineers must hover to keep running, to products that are capable and reliable enough to be commercially produced. Evidence of their use in clinical settings could certainly support this goal.

Knowledge in the Service of Society
While academic institutions seek to increase knowledge for its own sake, they also seek to place that knowledge in the service of society. To the extent that the government, in seeking input on this initiative, shares the same goal, it seems reasonable to tailor funding mechanisms to encourage or even require the commercial use of the results.

The Bayh-Dole Act "march-in" provisions actually allow the government to reassign IP generated by its funding if, at the agency level, it is determined that the "action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use" (35 U.S.C. § 203). While this has never been exercised, it's hard to imagine a more acceptable situation than when government-funded intellectual property designated to help those suffering from a rare medical condition has failed to deliver on the promise.

Grand Challenge Through Centers for Medicare & Medicaid Services (CMS)
Current reimbursement for prosthetic devices is governed by the "L-codes" for durable medical equipment set by CMS. Interestingly enough, although there is no reason other than convenience for it to do so, government procurement of these devices provided for veterans and active duty military through contractors (the majority of arms) are likewise priced according to these L-codes.

The procedure for creating new CMS L-codes and setting reimbursement levels for them is far from transparent. The list of codes reads like a partial catalog of devices: "Otto Bock Speed Hand, or Equivalent," for example. Because of this, the codes encourage a "race to the bottom," and many competitors products are simply cheaper devices that provide the same limited functionality, increasing providers' profit margins and offering patients nothing more than the original products.

Imagine if CMS were to offer the guarantee of reimbursement for a set number of patients through Medicare for a device that met certain performance criteria. Then, for a known outlay of government funds, the government could guarantee that the funds would only be spent if the devices reached market. While this doesn't guarantee that it would happen, it does guarantee that the money would not be spent unless it did. This strategy could certainly be part of, or even represent the culminating test of an annual competition and ongoing grand challenge.

Targeting STTR/SBIR Funding
To the extent that some government-funded intellectual property has gone unexploited by the

recipients of funding, STTR and SBIR funding mechanisms are a great way to encourage commercial development. That said, quite a number of prosthetic projects have gone through Phase II never to reach Phase III, where commercial funding is required. Bayh-Dole march in in these cases is a viable option as well, and perhaps even more justified, given the commercial focus of these mechanisms.

Alternatively, STTR/SBIR funding could be targeted at further developing open platforms such as that described in this document. Such funding could be dedicated toward creating commercial products based on such platforms, or on technology developed under other funding sources that has never been commercialized.

SVDOSB Set Asides
The government routinely favors Service Disabled Veteran Owned Small Business in contracting, and it stands to reason that such preferences could be extended to companies applying for research grants or contracts to help develop assistive technology, particularly when those vets represent the community that the funding is intended to serve.

From personal experience, I can relate an instance in which a reviewer heavily criticized a prosthetic arm-related SBIR proposal from a business perspective because the prosthetic arm market was so small. Obviously, if such funding mechanisms are to be targeted at underserved patient populations, any such concerns must be waived in advance, or STTR/SBIR mechanisms should be created specifically to target these markets.

Workforce development
I spend a lot of time telling students that prosthetic arms are not as advanced as they think that they are, and that they are unlikely ever to find a job as a prosthetic engineer, because there are so few of them. That has done little to dampen most of their enthusiasm, and it's an enthusiasm that we should channel. In general, students are extremely motivated to work on social problems, and we should figure out a way to try and put them productively to work.

If we are going to require that students spend countless hours working on a capstone engineering project to get their accredited degrees, we might as well put them to work on a problem that matters to society, and make sure that their work actually helps solve the problem. Along the way, we might teach them what it takes to keep a design history file, conduct a clinical trial, or properly document a manufacturing process to maintain FDA standards.

There is work to be done in creating and using an open, model process for creating an FDA-approved product that would otherwise never be created, in order simply to show others the way that such a process should be run and documented. Imagine the excitement of community college technology education students participating in machining and assembling parts for a prosthetic arm prototype designed by an engineering undergraduate, supervised by an engineering management or business school graduate student with experience in the medical device industry, all as part of a documented FDA-compliant process.

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7 September 2009

To whom it may concern:

I am the Director, Product Design, for Liberating Technologies, Inc. (LTI). Our company is an off shoot from a research project at the Liberty Mutual Insurance Company Research Center that began in 1973, but in 2000 LTI became a separate company. Most of our personnel date back to the previous team at Liberty. For thirty years, we have designed and distributed upper extremity prosthetic components. LTI manufactures the Boston Digital Arm, the only commercially available product that can monitor and control 5 motors and their associated control channels. LTI also imports and distributes a wide range of orthotic and prosthetic products.

Due to LTI's interest in controlling multiple devices, I proposed in 2002 that a task force be set up to write the specifications for an open-source industry-wide standard for using a bus to communicate between multiple devices. A researcher in Norway agreed to try to coordinate the efforts of the many groups that supported this effort at the initial meeting at the University of New Brunswick. This effort foundered when funding did not materialize.

When the open-source bus was proposed, there was only a little research activity in upper extremity prosthetics. Since then a number of new players have entered both on the research and development side, sponsored by DARPA, and on the commercial side with the advent of the ILimb Hand. Now, instead of only three or four degrees of freedom, people are talking of controlling 20 or more. Furthermore, there is now a major effort to use pattern recognition to squeeze more control information out of muscle signals. For instance, at the present time there are subjects who can control three or more functions in both directions with only three muscles. And they can do so in a natural way by attempting to do with their bodies what they did prior to amputation.

With an open-source bus, one manufacturer can develop the ideal signal processor while others develop hardware to use the control information generated. This effort will only succeed with a common control bus to move information from the source to the output devices.

At present there are several research efforts all implementing different digital standards for prosthetic arm component control, some of these are leading to products that are intentionally incompatible with the products of competitors. These initiatives will serve to further segment an already very small market, reducing choice for consumers and reducing market share for smaller manufacturers such as LTI. Many of these efforts have been almost wholly funded by US Government money, including the funding for the commercialization efforts.

The U. S. government is in an ideal position to push the industry toward a standard bus. Both of the current DARPA arm research projects use the automotive CAN bus standard for communication, but they are not yet compatible with each other. Further, one of these projects involves a foreign manufacturer large enough to block further innovation in this field if it uses a non-standard bus with the commercial version of the devices. LTI believes that government sponsored research should benefit large a number of companies as possible. With an open standard, LTI and the other small, innovative groups in this country can concentrate on designing components and control modules that will benefit amputees everywhere.

As the person who initially proposed an open standard, I am willing to help in any way possible to see that the research now being sponsored by our government leads to products that benefit as many amputees as possible. I would like to see the United States get its share of the world prosthetics market, and an open bus standard will certainly help us to do so.

Respectfully,

T. Walley Williams, III
Director, Product Development
[redacted]

September 8, 2009

To whom it may concern:

As the President of Motion Control, a manufacturer of powered arm components, including the Utah Arm elbow, electric hands, and the Electric Terminal Device (ETD) electric hook. Currently, our components are generally compatible with those of other manufacturers through an analog connection and control standard that has been used by the industry for a few decades.

It is becoming clear that for successful integration of electronic devices we all can foresee for the future, digital communication will be necessary. We think it will be important that future developments adopt a common communication standard, so that future components can all "talk" to each other, and allow consumers to choose components from all manufacturers. This standard is especially important for efforts which are
funded by the US Government money. We feel that the recipients of government funding for prosthetic component development should adhere to an open control standard for products created using those funds – the result will be a net lower the cost of innovation, and greater choice in the marketplace. This is more than just consumerism – this actually can effect the rehabilitation of persons with severe life-long disabilities.

As an example, both of the current DARPA arm research projects use the automotive CAN bus standard for communication – i.e., the hardware is there, but the two projects are not yet compatible with each other. By following an open standard these newer developments would more likely be compatible with each other, as well as with new products developed by other US developers in our industry.

Open architecture for prosthetic arm control is a good idea for consumers, and a good idea for most manufacturers.

Yours truly,

Harold H. Sears

Harold H. Sears, PhD
President
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