Responses to Questions for the Record
Pertaining to the Testimony of Jeffrey P. Sutton, M.D., Ph.D.

"NASA's International Space Station Program: Status and Issues"
Heard on April 24, 2008 before the

Subcommittee on Space and Aeronautics
Committee on Science and Technology
U.S. House of Representatives

Questions for the Record Submitted by Chairman Udall

1. Your prepared statement refers to "*strategic goals the ISS can fulfill in the area of biomedical research to address exploration needs*." Could you please elaborate on these goals, the progress being made to date, and what more needs to be done to achieve these goals?

Two broad strategic goals are outlined in my prepared statement regarding the International Space Station (ISS) and biomedical research to address exploration needs. The first goal is that ISS serves, and needs to be utilized, as an invaluable platform for biomedical science and technology projects that are currently under way. These projects have substantial promise for yielding results, countermeasures and technologies that will enable safe human exploration of space. Some of the projects are ground-based studies that are working their way through a product pipeline toward ISS flight testing and evaluation over the next several years. Other projects are presently ready for flight definition and study aboard the ISS. As ISS nears completion and research capabilities grow, it is strategically prudent to capitalize on investments made in the current portfolio of research and technology development.

A second goal is to take advantage of the efforts associated with the first goal and foster new opportunities in biomedical research and development for exploration. One area to look at is emerging partnerships between academia and industry, where there has been positive activity to share costs on projects. Another area of opportunity lies in the integration and synergy among projects that make up an expanding portfolio of flight studies. Integration among projects is important and adds value to the scientific enterprise. It is also timely as the depth and breadth of ISS capabilities as an orbiting, microgravity laboratory expand. Moreover, integration fosters international cooperation, international crew participation, and can lead to new, unanticipated discoveries to advance knowledge and countermeasures to complex biomedical risks.

These two goals were presented in the context of the important role the ISS can have for biomedical research and exploration. There are other considerations as well. For example, beneficial information for exploration is gained on human performance, psychosocial adaptation and team cohesion while accruing operational experience aboard ISS. Furthermore, it should not be construed that the goals stated in my testimony are inconsistent with the goals and sub-goals put forth in the "2006 NASA Strategic Plan."

With this clarification in mind, it is laudable that progress in ISS biomedical research has been achieved, given the (1) challenges of conducting biomedical research in general, (2) constraints imposed by mass, power, volume, cost and crew time, (3) impacts from the Columbia tragedy, and (4) limitations imposed by performing research within a facility simultaneously undergoing construction. Progress in specific areas is summarized in my prepared statement, which provides references for the principal U.S.-sponsored biomedical experiments aboard the ISS. Ground-based projects that are ready for, or in the process of maturing toward, ISS testing and evaluation, are also listed with references.

Regarding matters that need to be addressed in order to achieve the goals, it is vital to have adequate and consistent funding to enable continuity in science and technology efforts. At present, there is a small but critical mass of outstanding and dedicated investigators from across the nation, who are conducting necessary investigations to enable safe human exploration of space. These investigators are scientific, technical and educational leaders, who are at the forefront of their fields and are at premier academic institutions, biotechnology companies and government laboratories (NASA and other agencies). They have the unique, collective expertise to drive U.S. achievements in space biomedical research forward, while at the same time inspiring and training the next generation of scientists, engineers and physicians. It is therefore important that their projects and teaming with each other, with younger investigators entering the field, and with the operational community at NASA be sustained and appropriately augmented as ISS capabilities expand.

Along similar lines, as NASA looks to implement memoranda of understanding with other federal agencies, such as the National Institutes of Health, new appropriations for collaborative ISS research should be considered. These new appropriations are also relevant to the success of the ISS National Laboratory. It is not apparent how ISS science endeavors can be implemented by relying only on funds redirected from within agencies with relatively flat budgets.

In strengthening the pipeline of biomedical research that requires ISS utilization, it is further recommended that NASA permit the National Space Biomedical Research Institute (NSBRI) to be more engaged in transitioning and managing science and technology development for the ISS. The 1996 NASA Cooperative Agreement Notice 9-CAN-96-01, "Soliciting Proposals for the Establishment of the National Space Biomedical Research Institute," states in Section 7.0, and reiterates in Section 10.4, that "it is NASA's intent that responsibility for all appropriate NASA-sponsored Space Station human experiment opportunities be transferred to the Institute." Although NSBRI is NASA's primary partner for biomedical research, and has multiple international collaborations, NASA has not utilized the resources and expertise of NSBRI to help review, select or manage research for the ISS. This is an area that should be revisited.

2. **NASA has developed a Human Research Program Utilization Plan for the ISS, which identifies the risks for human exploration of space and the research on the ISS that can help mitigate the risks and lead to the development of countermeasures.**

a. Do NASA's current plans for ISS utilization enable the agency to adequately address the risks outlined in the plan and to develop countermeasures?

NASA's "Human Research Program Utilization Plan for the International Space Station" identifies 25 human health and performance risks requiring the ISS in order to perform research needed to quantify the risks and validate countermeasures and technologies. For each risk, there is a brief description of the planned activities and a top-level schedule, wherein a significant portion of the proposed work will be completed by 2016. Some risk assessment and countermeasure validation will occur beyond this date.

As stated in the document, the plan is subject to change based on multiple considerations. Nevertheless, in its current instantiation, the plan summarizes important risks and the development of countermeasures. Some risk areas are described in more detail than others, but in general, limited information is provided in the document.

NASA's current plans for ISS utilization enable the agency to address the risks. The question is what constitutes *adequate* risk mitigation? It is apparent that a more detailed, integrated utilization plan is needed to ensure as much progress and success as possible within the proposed time frame.

b. If not, what else needs to be done?

Items to be done are listed as recommendations for the Human Research Program Utilization Plan for the ISS:

- Prioritize the risks into categories to identify those among the 25 that are the most urgent to mitigate utilizing the unique capabilities of the ISS;
- Expand each risk section to provide a more comprehensive listing of proposed research, countermeasures and technologies;[1]
- Characterize the current pipeline of biomedical projects feeding into, and already approved as part of, the portfolio of research, development, testing and evaluation to be conducted aboard the ISS;
- Identify current science and technology gaps in the risk reduction plan utilizing the ISS;[2]
- Outline the flight resources and manifest opportunities;
- Describe current and planned experiment hardware and associated engineering needs;
- Discuss opportunities for integration and added value among studies addressing different risks;[3]

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[1] For example, ISS research to address the first risk in the plan, "Risk of Inability to Adequately Treat an Ill or Injured Crew Member," is scheduled for FY 08, 09 and 11. It would be helpful to list all relevant technologies at high readiness levels for flight that are candidates for testing and evaluation aboard ISS. Near infrared spectroscopy for non-invasive blood and tissue chemistry, and in-flight blood lab-on-a-chip technology for astronaut health monitoring are two such technologies. While both projects are currently funded by NSBRI, neither project is identified in the plan.

[2] This is important to do now as there is often a significant lead time to procure the needed studies and mature them to ISS-ready status.

[3] For instance, NSBRI is supporting a project to develop an ultrasound catalog for autonomous medical care. The catalog will provide, among other deliverables, an atlas of normal human anatomy and physiology acquired using

- Depict the roles and extent of industry involvement in the enterprise;
- Estimate the crew time dedicated to participate in research activities;
- Describe the metrics to be used to assess risk mitigation effectiveness and outcomes for the planned ISS activities;[4]
- Address plans for data sharing;
- Address plans for how intellectual property will be handled;
- Expand on issues concerning ISS partner participation;
- Discuss how research, development, testing and evaluation will be supported.

3. In your prepared statement, you indicate that affordable and reliable access to and from the ISS are key to the success of conducting biomedical research. You go on to say that critical to this success is the availability of cost-effective transportation services. How critical is a down mass capability for biomedical research?

The physical return of samples and other materials is critical to the success and reproducibility of biomedical experiments aboard the ISS. Down mass capability is essential to guarantee the quality of certain types of biological specimens (fluids, cells and tissue) being returned to Earth. Access to powered, large-volume, pressurized lockers for transport is necessary.

Given the need for this capability, whenever possible, it is anticipated that on-orbit resources would be utilized to characterize findings, and that digital data would be down-linked to Earth. In my verbal testimony, I referred to the successful use of on-orbit ultrasound to perform medical imaging on ISS crew members. Streamed video and still images of clinical quality from a series of studies were obtained without the need for down mass capability.

The U.S. orbiter and the Russian Soyuz have served as the primary means to ensure safe return of biomedical samples from research conducted aboard the ISS. Both vehicles are capable of providing powered middeck locker return, when necessary, for valuable experimental materials. It is desirable to have configurable soft-packs when power and/or pressurization is not necessary.

The transfer vehicles in development by international partners (the European ATV and the Japanese HTV) do not provide down mass capability. Although these vehicles play an important role in delivery of cargo to the ISS, their utility for transferring experimental samples and other materials from the ISS to Earth is absent. Similar to the conditions provided by the orbiter and Soyuz, the Space X Dragon capsule, currently under development for NASA's Commercial Orbital Transportation Services program, is expected to be able to accommodate both

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ultrasound aboard the ISS, starting with Expedition 6. Studies should continue on this project which addresses multiple risks, including but not limited to the “Risk of Inability to Adequately Treat an Ill or Injured Crew Member,” “Risk of Accelerated Osteoporosis,” “Risk of Cardiac Rhythm Problems,” and “Risk of Intervertebral Disc Damage.”

[4] All projects within the Human Research Program can be assigned countermeasure and/or technology readiness levels. The rate of change of these levels with time provides an estimate of when projects are ready for flight testing and evaluation. Not all projects mature to flight and some projects enter the system as flight studies. There are also other measures to characterize the pipeline beyond readiness levels and their time rate of change.

pressurized and non-pressurized cargo in a middeck locker-like configuration. Other developments are also in progress.

4. Given your experience in leading an institute that involves universities, Federal agencies, and industry in conducting research to support human space exploration, what should NASA consider as it explores options for managing the ISS National Lab?

NASA should consider management options for the ISS National Lab that have been successfully implemented in other large-scale, ambitious research and engineering projects of national and international importance. Within NASA, excellent examples include the Apollo and Hubble Space Telescope programs. There are many non-NASA examples, including the Manhattan Project, which exemplify how outstanding scientists have been brought together to work on teams, with an upper-level management structure guiding and integrating teams to achieve a single common purpose of paramount significance.

There is not necessarily a single, best way to manage the ISS National Lab. Substantial resources exist, and more are being put into place, aboard the ISS. There is a wealth of biomedical research and technological infrastructure within universities, medical schools, industry and government laboratories to enable ISS National Lab achievements. As mentioned previously, there is a cadre of outstanding investigators who have, and students who are acquiring, the necessary skills to generate productive and meaningful discoveries in space, in partnership with ISS crews. Funding, reliable access to and from the ISS, and international limitations are challenging issues but fundamentally solvable.

Two items that NASA should focus on regarding management are requirements and leadership. A strategic and tactical plan that is consistent with, but includes more detail than the reports presently available on the ISS National Lab, should be developed, with particular attention paid to requirements. The management options are narrowed by considering only those systems that allow the requirements to be met. In formulating the strategic and tactical plan, it can be useful to assemble a small working group of NASA and non-NASA experts, whose membership includes experience in leading large scientific institutes, conducting basic and applied biomedical research in space, partnering with industry and successfully implementing international science and technology programs. Attention should be paid to the needs and expectations of key stakeholders, and the plan should be thoroughly vetted before being implemented.

Leadership is a key consideration for success in managing the ISS National Lab. The Director should possess not only the necessary credentials, experience, skills and integrity to perform his or her duties, but must also have a bold vision for the ISS National Lab that is embraced by NASA, other federal agencies, Congress, and to the greatest extent possible, the American public. The ISS National Lab must have a strong leadership team to effectively implement the strategic and tactical plan, and to modify the plan accordingly, in order to achieve maximum return on, and benefit from, our Nation’s investment in the ISS and its precious resources.

<u>Questions for the Record Submitted by Representative Feeney</u>

1. **At the hearing, you outlined a number of initiatives conducted by the National Space Biomedical Research Institute related to developing countermeasures for long-term human exploration of space. Which among these has generated the most promise, and which, in your opinion, continues to pose the greatest challenges?**

Ten NSBRI-sponsored science and technology projects, all generating substantial promise, are highlighted in my prepared statement. Three are described in more detail here to illustrate the extent of promise within NSBRI's portfolio. This is followed by remarks concerning an NSBRI initiative, which despite considerable promise, poses great challenges.

NSBRI took a strong position in enhancing near-infrared spectroscopy analysis and subsequently developing a small, lightweight, portable means of performing non-invasive blood and tissue measurements for use in space.[5] By assessing tissue pH and lactic acid in real-time during exercise, it is possible to adapt exercise countermeasures and efficiencies for individual crew members. This device has been tested on astronauts exercising at Johnson Space Center, and the technology is maturing toward evaluation aboard the ISS. There are medical applications for space exploration (e.g., assessing tissue viability in the case of a crush injury or exposure to extreme temperatures) and applications to health care on Earth (e.g., assessing the microvasculature in diabetics).

Light in the blue part of the spectrum is being used as a countermeasure for performance errors associated with circadian desynchronization, sleep loss and adaptation to shifts in work schedule. NSBRI has sponsored research published in leading journals, such as *Science* and *Nature,* delineating mechanisms associated with blue light effects. The Institute has also taken the lead in developing, testing and evaluating the countermeasure in operational settings, and in working with NASA to modify the lighting in designs for the crew exploration vehicle. There are several applications of this countermeasure on Earth.

NSBRI assessed the utility of several portable medical imaging technologies (dual energy X-ray absorptiometry, magnetic resonance imaging, diffuse optical tomography and ultrasound) for use in space. In partnership with NASA, a series of elegant studies were performed aboard ISS using ultrasound, which has become the medical imaging technology of choice. NSBRI therefore shifted its portfolio to reflect the promise of ultrasound, and currently supports novel countermeasure development projects using scanning confocal ultrasound and high-intensity focused ultrasound (HIFU). HIFU shows particular promise in addressing the risk of inability to adequately treat an ill or injured crew member. NSBRI has co-sponsored, with the Department of Defense, a small portable ultrasound system capable of sensing and then (using autonomous image guidance) performing non-invasive surgery with HIFU.[6] This countermeasure, employing an integrated sensor-effector platform, has applications on Earth in emergency medicine and on the battlefield.

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[5] The device is reminiscent of the medical tricorder used by Dr. McCoy in the fictional series *Star Trek*.
[6] See http://www.nsbri.org/Research/Projects/viewsummary.epl?pid=158

One of the most challenging risks to mitigate, for human space exploration, is the harmful effects of radiation. A recent report from the National Research Council, entitled "Managing Space Radiation Risk in the New Era of Space Exploration" (2008), provides an insightful assessment of the risk and efforts to protect against exposure to space radiation. NSBRI supports NASA's radiation program in several ways.[7] The Institute funds the development of gas and solid-state dosimeters for real-time assessment of radiation exposure to astronauts. This is particularly important for missions beyond low Earth orbit. A number of projects on NSBRI teams, such as those dealing with bone and the cardiovascular system, have a radiation component. Countermeasures are being investigated to protect against the harmful effects of radiation to these and other systems.

Perhaps the most significant contribution of NSBRI in addressing radiation risks is a new initiative addressing the mitigation of effects due to acute radiation exposure. In February 2008, NSBRI released an announcement "Research Opportunities Soliciting an NSBRI Center of Acute Radiation Research for Ground-Based Studies on Acute Radiation Effects."[8] The goal is to develop countermeasures to acute effects that could potentially compromise crew members and even the mission itself. Countermeasure development in this area is challenging, but it is an essential part of supporting long-duration, human exploration of space.

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[7] It is worth noting that NASA's radiation program, within the Human Research Program, is supported at an amount that is 50% greater than the *entire* NSBRI. To accomplish its mission, the Institute relies on its ability to leverage resources in innovative ways.

[8] See http://www.nsbri.org/Announcements/rfa08-02.html