Written Statement

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U.S. House of Representatives
Committee on Oversight and Government Reform
Field Hearing

"Federal Policies Affecting Innovation and Job Growth in the Biotech and Pharmaceutical Industries"

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Executive Summary:

Good morning, my name is Alex Lukianov. I am the Chairman and Chief Executive Officer of NuVasive, a publicly traded medical device company focused on developing minimally disruptive surgical products and procedures for the spine. Our goal is to advance spine surgery by developing new products and procedures that provide superior surgical outcomes through shorter operations, less traumatic impact to patients, shorter hospital stays, and faster return to normal activity. I am also the Chairman of the Board of Directors for BIOCOM, a Southern California based life science association focused on initiatives that positively influence the region's life science community in the development and delivery of innovative products that improve health and quality of life. I am the Treasurer on the Board of Directors for the Medical Device Manufacturers Association or MDMA, a national trade association based in Washington, DC providing educational and advocacy assistance to innovative and entrepreneurial medical technology companies.

Enclosed you will find an overview of various items that have or will further slow advancements in patient healthcare. Slower FDA approval process, proposed healthcare reform with increased tax burdens and administrative requirements, and unpredictable payment practices of private insurers that result in the denial of needed care are having a direct impact on the ability of companies to develop new technologies. These factors are causing NuVasive to re-evaluate a number of operational issues including reducing research and development for healthcare advancements, decreasing new job creation, and potentially driving manufacturing, clinical trials and further expansion outside the U.S..

Company Background:

NuVasive is a public medical device company focused on developing minimally disruptive surgical products and procedures for the spine. The Company has grown from a venture capital backed start-up company to $500 million in revenue over the past decade. NuVasive is now the 4th largest spine company in the U.S. and the 5th largest player in the $7.7 billion global spine market.

This industry leading growth has been driven by a core value of Speed of Innovation™ which has propelled the company to a global presence employing over 1,000 people. From a technology perspective, our sole focus is to advance spine surgery by developing new products and procedures that provide superior surgical outcomes through shorter operations, less traumatic impact to patients, shorter hospital stays, and faster return to normal activity. NuVasive has had tremendous impact on changing patient lives with superior clinical outcomes that are faster, better and cheaper.

FDA Approval Process Summary:

Over the past 18-24 months, NuVasive has experienced longer delays related to FDA product approval in 510(k) and PMA clearances. Longer FDA approval times will potentially result in significant revenue loss estimated at up to $70 million over 2 years, increased operating expenses of over $2 million, hundreds of new jobs eliminated, and less investment in research and development. Still, we do not believe a major overhaul of the current FDA process is needed. Instead, we need process predictability and timeliness from the reviewers to ensure approvals are being efficiently processed under the current high safety standards.

- Historically, NuVasive has launched at least 10 new products per year. That number is being actively reduced to 50%.
    - Our recently-submitted PMA was expected to take approximately one year, and we now expect it will take closer to two years despite not having to go through an expert panel review. At the 100 day review for this device in March 2010, half of the assigned team from FDA did not show up for the meeting.
    - 3rd party study on FDA approvals shows that over the last 3 years there has been a 42% increase in approval times for 510(k)s and 93% increase for PMAs.[1]
- It is becoming far more efficient and faster to innovate outside the U.S. in such places as Europe. Non-U.S. systems have more timely, predictable and transparent processes. We have seen U.S. delays of 3-70 months[2] which has forced NuVasive to rethink longer term strategies around

[1] FDA device approval database; BCG Analysis: data cut by year of decision; PMA approvals only include original approvals, no supplements; 2010 data is pro-rated to obtain end of year numbers

[2] FDA impact onUS medical technology innovation, November 2010, **Aabed Meer** MD-MBA Candidate Stanford University, **Josh Makower, MD** Consulting Professor of Medicine Stanford University CEO, ExploraMedDevelopment, LLC Venture Partner, NEA

where to place research & development jobs and even whether or not to invest in innovation of new products.

- NuVasive has committed to fewer research & development projects in 2011 as a result of costs associated with protracted approval/clearance processes. This results in less innovation and has caused us to reduce hiring by at least 15% with 150 fewer new jobs for our 2011 projected headcount.

- Increased delays from FDA and country of origin restrictions have caused NuVasive to assess the viability of expanding manufacturing outside the U.S. which would result in potentially sending hundreds of new jobs out of the U.S.

- A University of Minnesota study funded by the Kauffman Foundation assessed the 510(k) approval process from a safety perspective and showed that 99.6% of 510(k)/PMA devices did not have a Class I recall in the last 5 years.

  Hall, R., Using Recall Data to Assess the 510(k) Process, Public Health Effectiveness of the FDA 510(k) Clearance Process: Workshop #2, Institute of Medicine, Washington, DC, July 2010.

The following outlines discreet examples of product delays NuVasive has experienced over the past 12+months, as well as proposals for changes to ensure patient access to the best possible solutions continue to be timely.

- A 510(k) product for a bone substitute device which is a combination of 2 cleared 510(k) predicates. Additional testing requests by FDA will now delay this product by over 12 months potentially resulting in lost revenue of ~$20 - $30M, additional testing costs of nearly $1 million and significant loss of profit to be invested back into business.

- PMA cervical total disc replacement device was submitted for approval in Q1 2010 with an expected review process of approximately 1 year due to an expert panel review not being required. NuVasive now estimates approval could be delayed to 2012 due to additional review time and pre-clinical testing requirements, costing approximately $1 million. The Company expects to experience potential revenue loss of ~$25 million due to the delay. This product has been commercially available in Europe for over 5 years with ~10,000 devices implanted with safe and efficacious results.

- Multiple other 510(k) products in 2010 have been delayed for requests such as additional testing despite the lack of predicate safety concerns. NuVasive estimates significant additional lost revenue and testing costs associated with these delays.

- NuVasive's NeuroVision 510(k) for nerve monitoring was granted nearly a decade ago. Since then, nearly 150,000 cases have been successfully performed. On submission of a new 510(k) for a next generation nerve monitoring system (already cleared in Europe, Japan, and Asia Pacific) the FDA sought to re-open the user interface of the original NeuroVision to reassess the predicate. Actions like this would lead to significant loss of revenue and added expense despite having no safety issues.

NuVasive and other medical device companies appreciate the importance of patient safety. Successful medical device businesses are built on safety records. We seek to maintain the FDA's high standards for safety that have resulted in a strong record of approving safe products in the past while allowing much more efficient and timely access to care. FDA is a valued regulatory partner to private industry, and we are not asking for less involvement, just a more efficient, timely and predictable process. NuVasive requests the following:

- **The establishment of clear submission requirements for both 510(k) and PMAs through periodically updated guidance documents, pre-meetings to set expectations, and requirements that survive the device's approval cycle;**

- **A return to a predictable and clear review process where there is strong interactive collaboration with reviewers and timelines are adhered to. Clear checkpoints of 30 and 60 days for 510(k)s are critical and similar 100, 140, and 180 day progress updates for PMAs;**

- **510(k)s cleared in 90 days without clock "manipulation" (NSE decisions leading to new filings do not reflect aggregate time from prior filing) and similarly PMAs approved in 1 year when an expert panel is not required.**

Healthcare Reform Impacts (Medical Device Tax):

The U.S. medical technology industry leads the world in innovation and is a major driver of the U.S. economy as well as U.S. global competitiveness. The U.S. was once a beacon of innovation, driving new ideas & technology and attracting the best and the brightest. While other technology sectors are losing their competitiveness & increasingly outsourced,[3] Med Tech remains strong after decades of research and development investment. The U.S.'s lead in Med Tech innovation is expected to lose ground, however, with countries like China, India & Brazil expected to experience the strongest gains[4] based on policies that encourage investment into research and development.

- **Med Tech is leading exporter and major driver of U.S. economy.** Medical Device creates ~2M jobs in the U.S. with a salary ~40% higher than the national average. In 2008, U.S. Medical Technology companies shipped $136B in products globally, directly employing nearly 425k individuals (and indirectly impacting another ~1.5M jobs in manufacturing, suppliers, and service providers) and paying $24.6B in salaries with an above average wage of ~$60k/year.[5] Internationally, the US is the world's largest producer (as well as consumer) of medical devices, one of the few industries with a trade surplus estimated at $5.4B in 2007.[6]

[3] "The Atlantic Century: Benchmarking EU & US innovation & Competitiveness", The IT & Innovation Foundation, February 2009. The US ranked 6th among 40 nations (down from 1st in previous studies). [Other surveys which use opinion survey data can lag due to reputation. For example, The US was ranked 1st in the World Economic Forum's "Global Competitiveness Report 2008-2009" and IMD's "World Competitiveness Yearbook", both which rely heavily on survey data.]

[4] "Medical Technology Innovation Scorecard: The race for global leadership", Price Waterhouse Coopers survey, January 2011.

[5] "State Impacts of the Medical Technology Industry", The Lewin Group, June 7, 2010. 1.5M additional jobs is estimated, based on 1.6M reported in the 2007 Lewin Group report.

[6] "Medical Devices Industry Assessment", International Trade Administration, 2009.

- In California alone, Med Tech employs over 80k individuals, with $5.3B in payroll and $26.3B in revenue. This results in ~210k additional jobs, driving an additional $6.9B in payroll and $31.6B in revenue.

- Med Tech innovators are moving overseas for manufacturing, clinical data, new product registrations and sales. International regulatory processes offer timely, predictable, transparent & cost effective processes. While Med Tech in the U.S. is under fire and the obstacles to research funding are increasing, investment and know-how is moving overseas and incentives for long term investment are evaporating.

- As part of the 2010 health reform legislation, medical device manufacturers will be required to pay a new 2.3% excise tax on all FDA approved devices sold in the U.S. The tax is punitive in nature and will likely raise costs throughout the healthcare system. Companies will be forced to reduce jobs and research and development investment. This will not only harm the economy, but more importantly it will harm patients. Because the tax is based on revenue, successful rapidly growing companies will be hardest hit, making it more difficult to invest in growth & innovation.

- Ironically, it is the successful rapidly growing companies such as NuVasive that will be hardest hit, in some cases just as they are beginning to generate profit. Med Tech is making decisions today to address the expected tax, including less dollars for research and development and new jobs, and more pressure to outsource & invest overseas. This dynamic is causing companies like NuVasive to focus much more heavily on international markets. Wall Street estimates predict that large cap companies will have up to a 5% decrease in profitability while small to mid cap could see 10-15% decrease. Using 2011 revenue projections, NuVasive would be required to pay over $12M equating to an approximately 14% reduction in operating profit. This type of increased tax burden will potentially result in over 100 new highly skilled jobs eliminated.

- Supporters of the medical device excise tax claim that there will be a “windfall” for medical device companies as newly-insured beneficiaries will enter the healthcare system. This is likely not the case as many medical devices are used either in the acute care setting or in an already-insured patient population, such as Medicare. Moreover, previous experience in states like Massachusetts, which has near-universal coverage, suggests that there will be no additive benefit in reimbursement.

- President Obama, in his recent State of the Union address, stated that we need to “out-innovate, out-educate, and out-build the rest of the world.” The first step to “Winning our Future (via) Innovation” must start with Med Tech where the US leads global innovation and where we still retain the expertise & critical mass to retain that lead. The goal of Health Care reform is to ensure that the best medical solutions are applied in the most efficient and cost-effective ways, not to penalize the companies that contribute to better healthcare & healthier more productive lives.

- **The Medical Device Tax must be repealed if we are committed to "Winning the Future (via) Innovation". Several bills in both the House and Senate have recently been introduced to repeal the medical device tax. Congress should move forward with a repeal of the tax as it will prevent harm to both patients and innovative companies contributing to economic growth in the U.S. The repeal of the Medical Device Tax is critical to ensure that Med Tech remains a global innovate on leader and a critical piece to "Win our Future".**

Healthcare Reform Impacts (Sunshine Act):

- Another component of the healthcare reform legislations is the Physician Payment Sunshine Act which requires disclosure of monies or items of over $10 in value given to Health Care Professionals. Industry does not disagree that HCPs should disclose such payments, but the threshold established will create an administrative burden diverting company resources and increased spend. Medical device collaboration with surgeons is far different than other industries like pharmaceuticals. The surgeon is a key component in the development of new products, training of other surgeons and providing product feedback to medical device companies on pilot launches. Currently, there are a handful of states which have already implemented disclosure requirements. The problem is that each state is different than the other which also creates an administrative burden for the industry.

- **Surgeons play a critical role in the continued innovation and advancement of medical technology and federal disclosure legislation should be written in a way that allows for our unique research and development process to thrive while providing meaningful information regarding payments to physicians in an appropriate context. We propose that disclosure requirement dollar limits are increased to a reasonable threshold such as $10,000 per HCP and to delineate types of disclosures across training/proctoring other surgeons, research and development consulting. Finally, it would best to create a single federal statute vs having individual state policies which are administratively a burden to medical technology companies.**

Healthcare Reform Impacts (Reimbursement):

Over the last 12 months, the spine industry has seen an alarming increase in private insurance companies reducing patient coverage and denying spine surgery for legitimate and necessary treatment. Increased documentation and stricter approval criteria are now the norm, driven by benefits managers who are tasked to decrease utilization.

80% of Americans experience back pain during their life, of which 10% is chronic or recurrent, interfering with employment & quality of life. The cost is significant, with an estimated $100B in direct & indirect costs including lost days of work, and the majority of these costs (80%) due to the 20% of patients that are disabled. Over recent years, innovation has revolutionized spine surgery, offering patients with debilitating pain a return to active productive lives, with success equivalent or superior to the success of

hip replacement. Spine surgery has proven its value to society and recent activity by Insurers to get between surgeons and patients and interfere with patient access to the medical care necessary to return them to active & productive lives must be addressed.

Denials are frequently based on the 3rd party actuarial guidelines that were created with no involvement from relevant medical societies and without consideration of the most recent technological advancements. Their task was simple. Manage utilization and risk for insurance companies. Insurers profit while patients suffer. Such activity has spurred an unheard of response, with 9 surgical societies collaborating on a joint letter in the case of Blue Cross Blue Shield of North Carolina (BCBS NC), to protest insurer coverage changes and cite evidence in support of fusion. While BCBS NC revised their policy to be more in line with the societies' recommendations (and expressed a willingness to approve certain fusion cases through the appeals process), it is still the Insurer guidelines rather than guidelines set by the relevant medical societies that are used to define patient care and drive a labyrinth of administration & documentation that the surgeon's office and patient must navigate for approval.

Data studies demonstrate the effectiveness of spine surgery over conservative care, in particular for minimally disruptive techniques where minimal trauma translates to superior patient & economic outcomes with lower blood loss, shorter operating time & hospital stay, faster recoveries, fewer complications and lower post-operative care requirements. Even higher risk patients (including elderly & obese patients) and more complex indications (such as degenerative scoliosis) show successful outcomes. In addition to better outcomes, a recent study notes a 10% reduction in hospital costs for minimally invasive surgery (MIS). Meanwhile, newer technologies offer improvements to past treatment options, such as total disc replacement (TDR) shown to be superior to fusion for some indications.

The impending Healthcare Reform legislation is creating an environment of extreme uncertainty throughout the economy. Patients in need of life improving procedures are feeling the effects of this first hand, as legitimate and necessary treatment is increasingly denied by private insurance carriers based on actuarial guidelines. In the end, it is the patient that suffers as physicians spend valuable time wading through the administrative quagmire created by the private payers. Patients are being out right denied access to clinically supported procedures and some physicians are forced to leave patients in pain or are forced to use less efficacious treatment options.

- **Doctors, not consultants nor unrealistic guidelines, should determine the appropriate care for their patient. Surgeons must be given the latitude to make decisions based on what is best for their patient and taking into account patient vocation, ability to withstand chronic pain and lifestyle. Guidelines cannot (nor are they meant to) substitute the judgment of an experienced & skilled surgeon familiar with the patient's diagnosis, needs & treatment options. Insurers must be accountable via transparency of pre-approval requirements, documentation and decision rationale, with consequences for denying needed medical care.**

Patient Testimonials:

It is the American patient and industry that suffer from inefficiencies in the system. NuVasive has created products and resources for those suffering from chronic back or leg pain by educating patients and clinicians about surgical treatment options. I, myself suffered from chronic back pain for years enduring debilitating pain which greatly reduced my quality life. I can tell you first hand that spine surgery truly changed my life and for that I am immensely grateful.

Below are some testimonials of those that were able to benefit from the innovative technology NuVasive was able to bring to physicians for their treatments. The patients range from a Hall of Fame NBA basketball player, a UFC fighter, to the young, the old and anyone in between as back pain impacts all walks of life. In addition, we have been introduced to numerous patients who have travelled abroad to receive treatment options not available in the US. These patients sought access to new technology that has been used in thoU.S.nds of surgeries under a more efficient regulatory system. NuVasive believes the innovation of these new devices, and the corresponding investments and job creation, will increasingly seek out the markets and countries that provide the most efficient regulatory systems.

- NBA Hall of Fame player Bill Walton recalls, "I lived in this increasingly unbearable world of pain and disability." At one point, feeling like there was no hope, he stood atop a tall bridge and contemplated jumping. After undergoing going successful surgery through NuVasive's innovative products, Bill has regained his life back. "After a few months, I began to do things again I hadn't been able to do in years, like put on my own shoes and socks and bend over and pet the dogs," says Bill. "But it was right around the seven-month mark when I turned the corner and found freedom again, pedaling my bike with no limitations. Riding on the open road, the wind and the sun in my face—that was the greatest outcome in the world for me. I had lost everything and now I'm back in the game."

- UFC fighter Nate Quarry is no stranger to pain when it comes to having a successful mixed martial arts career, but even he was debilitated by the constant grinding pain. "I was in so much pain, I could hardly train at all. I was on all sorts of painkillers to get through the day. They just masked the pain. It was a path to nowhere. I couldn't even pick up my little girl because I was in so much pain." After learning that patients can experience less blood loss, a shorter hospital stay, and a faster recovery with NuVasive's innovative procedure as opposed to traditional back surgery, Nate underwent successful surgery and was back in the ring 15 months later. "My life was reduced so much because of the back pain. Now I have a new lease on life without back pain."

Thank you for the opportunity to outline some of the issues we are facing as a company, as an industry, as a nation. I am available to answer any further questions you might have.

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Alex Lukianov is the Chairman and Chief Executive Officer of NuVasive, Inc. Mr. Lukianov has over 25 years of experience in the orthopaedic industry, with 20 years in senior management. Prior to joining NuVasive, Mr. Lukianov held various executive positions with Medtronic Sofamor Danek, including President of USA. He also directed a business unit at Smith & Nephew Orthopaedics and managed an orthopaedic joint venture between Stryker and Meadox Medical.

Mr. Lukianov attended Rutgers University and served in the U.S. Navy. He is also the Chairman of the Board of Directors for BIOCOM, a Southern California based life science association focused on initiatives that positively influence the region's life science community in the development and delivery of innovative products that improve health and quality of life. He also serves as Treasurer on the Board of Directors for the Medical Device Manufacturers Association or MDMA, a national trade association based in Washington, DC providing educational and advocacy assistance to innovative and entrepreneurial medical technology companies.

Mr. Lukianov is also on the boards of Volcano Corporation, a publicly traded company that develops products that aid in the diagnosis and treatment of vascular and structural heart disease, and Ophthonix, Inc. a privately held company focused on vision high definition correction technology.

Mr. Lukianov has appeared on various television shows including Fox News, MSNBC and CNBC to discuss topics ranging from the future of innovative solutions in spine to advocating change in federal policies impacting growth and innovation within the life science industry. As a CEO of a public company, he has taken a leadership role to address issues in healthcare reform, including private payer reimbursement denials, medical device tax, the Sunshine Act, as well as delays in the FDA. In addition, Mr. Lukianov routinely participates as a panelist on numerous forums including the Corporate Directors Forum, the Phoenix Medical Device Conference, Venture Capital Forum.

Committee on Oversight and Government Reform
Witness Disclosure Requirement – "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

Name: Alexis V. Lukianov

1. Please list any federal grants or contracts (including subgrants or subcontracts) you have received since October 1, 2008. Include the source and amount of each grant or contract.

None

2. Please list any entity you are testifying on behalf of and briefly describe your relationship with these entities.

NuVasive, Inc. – Chairman & CEO

3. Please list any federal grants or contracts (including subgrants or subcontracts) received since October 1, 2008, by the entity(ies) you listed above. Include the source and amount of each grant or contract.

None

I certify that the above information is true and correct.
Signature: [signature]

Date: 4-19-11