Senate Committee on Commerce, Science and Transportation
Hearing on Competitiveness, Innovation and Export Promotion
"Innovation in America: Opportunities & Obstacles"

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Introduction – My name is Andrew Weiss, and I am the President and CEO of CoAxia, a medical device startup 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 US, 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 US 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 US. In my hometown of Minneapolis, there are 100's 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, US 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 1/3, 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 requlatory 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 US 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 US medical innovations flourish here in the US.

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 & 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 requlations 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 US 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 US 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 & 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 US, 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 judgement, 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 US 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 & 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 – 1000 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.