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Nanotechnology: The State of the Technology and Appropriate Federal Responses, from the Perspective of a Small Company

I thank Chairman Stevens and Co-Chairman Inouye for their leadership in holding this hearing on the Competitiveness of Nanotechnology in the U.S. Further, I would like to thank Senator Ensign for his support to ensure that Nevada is a nanotechnology leader.

I am Alan Gotcher, President and CEO of Altair Nanotechnologies, Inc. Altair ("Altairnano"), based in Reno, Nevada, is a leading supplier and innovator of advanced ceramic nanomaterial technology. Previously, I was senior vice president of manufacturing and technology and CTO at Avery Dennison, where I managed R&D, product development, manufacturing and lead the development and commercialization of several hundred-million-dollar new product platforms. I am also an inventor and entrepreneur.

The hyperbole surrounding nanotechnology is significant. And yet the potential of the technology is real. I wish to take this opportunity to address three core issues:

1. The State of the Technology: How it Looks from the Trenches

Nanotechnology can truly change our lives in many fundamental and positive ways. We have barely scratched the surface of what the science of nanotechnology might be capable. Today I will tell you how two of Altairnano's platforms—its Lithium-ion nano battery initiative and its chem/bio sensors—are on the verge of changing our reality.

2. The Responsible Commercialization of Nanotech Products: Altairnano as Steward

As this infant industry grows, we–like the chemical industry before us–must learn how to be good stewards of our environment. I will briefly outline our corporate commitment to product and environmental stewardship, and what we are doing to ensure that our products and manufacturing processes are safe.

3. The Role of the Federal Government: Ensuring the Global Competitiveness of the U.S. Nanotechnology Industry

All members of our national science and engineering establishment need to come together and partner with people in the nano industry in order to ensure that nanotechnology is researched and developed properly from the beginning. This will require a major commitment of federal resources, which will be an investment in our country's future competitiveness.

1. The State of the Technology: How it Looks from the Trenches

As I said earlier, the hyperbole about nanotechnology is tremendous, but the potential for this technology to change our lives in many fundamental and positive ways is real. To illustrate that point, I offer two examples of exciting technology that Altairnano has developed and is currently in the process of commercializing. In each instance, the Altairnano materials– specifically due to their "nano-ness"— provide revolutionary characteristics that are desired by the marketplace. In addition to stimulating significant national economic activity, these development programs at Altairnano will serve to protect and improve the environment.

My first example is Altairnano's advanced, rechargeable Lithium-ion ("Li-ion") nano battery. This product is a response to the increasing need and demand for more affordable, less-environmentally damaging energy sources. Consider the factors that are driving this demand:

- Pollutants emitted by conventional cars and trucks are making the air we breath increasingly unhealthy. (Recognizing this danger, many states are looking to follow California's lead by requiring low- and zero-emission vehicles.)
- Nearly half our consumption of imported oil comes from a dependence on conventional cars and trucks with internal-combustion engines.
- We need to win the quest for the production of a practical alternative-energy vehicle.

The solution? Altairnano has created an innovative, rechargeable Li-ion battery that will enable realistic production of a vehicle unlike any available today. Imagine a fully electric six-passenger car or full-size pickup truck operating on batteries that offer conventional acceleration and cruising speed. Imagine batteries with a range of 200 miles—and with a recharge time of just several minutes. And imagine batteries with twice the life cycle of anything comparable today—powering a vehicle for more than 100,000 miles.

Just last week, we produced and tested our first batch of Li-ion battery cells, utilizing the company's nano-structured electrode materials, at our Anderson facility just north of Indianapolis, Indiana.

Unprecedented Battery Performance

Testing has revealed that they perform at 90 percent of capacity at minus-22 degrees, Fahrenheit. Conventional Li-ion batteries and the nickel-metal hydride batteries used in hybrid electric vehicles become either sluggish or unable to charge at temperatures below freezing. In addition, unlike conventional Li-on batteries that risk spontaneous and catastrophic failure at temperatures above 266 degrees, the safety threshold for Altairnano's nano-structured lithium titanate spinel electrodes is 480 degrees, an important consideration for such extreme environments as aerospace and military applications. And, unlike current Li-ion batteries that contain hazardous chemicals and materials, the Altairnano battery designs and materials are intrinsically safe because they do not contain any toxic materials. This also makes them recyclable without any special needs.

As this performance shows, the infrastructure now exists for the creation of a high-performance, all-electric vehicle. This technology could be rapidly adopted by American automobile manufacturers, and is just around the corner. We are already in negotiations with top automobile, truck and bus manufacturers. Similarly, our technology is being evaluated by major manufacturers of hand-held power tools. Just imagine a power tool with twice the power of today's 18- to 20-volt tools at the same price point, and one that can be fully recharged while the worker grabs a cup of coffee. That, also, is coming soon.

Chemical/biological Sensors for National Security

My second example of how Altairnano's unique materials can change our world relates to national security. We have been collaborating with the universities of Western Michigan and Nevada-Reno to develop chem/bio sensor arrays capable of detecting the presence of a wide spectrum of potential explosives, chem/bio weapons and illegal drugs. These arrays, made possible by Titanium Dioxide (TiO2) base technology unique to Altairnano, have been successful beyond our wildest expectations. Not only are they capable of sensing the presence of low levels of potential explosive and chem/bio hazards, they're also able to report this information to a local display or a remote monitoring station.

With the help of scientists and engineers at Genesis Air Technologies, we have also learned how to use these and similar materials to destroy target chem/bio agents introduced into, for example, a building's HVAC system. The application of this technology can provide protection against most airborne health or environmental hazards. These materials are now being incorporated and tested by Genesis Air in systems designed for "smart" buildings. Clean, safe air

with a built-in early-alert system in the case of adverse action: It's within sight, thanks to nanotechnology.

2. Responsible Commercialization of Nanotech Products: Altairnano as Steward

Altairnano is strongly committed to a position of good stewardship. This includes concern for the safety and welfare of our employees, our customers and strategic partners. *Employees and consumers should be shielded from exposure to nanoparticles at every point along a product lifecycle.* That is why we are dedicated to creating "safe" products—safe for individuals and safe for the environment.

Altairnano-NIOSH-University of Nevada Collaboration

Since the fall of 2005, Altairnano has been working closely with scientists at NIOSH and the University of Nevada-Reno to monitor air quality in our Reno facilities. Ultimately, the two goals of this program are to ensure minimal–or zero–worker exposure to fine and ultrafine materials in the workplace, and to establish the basis (a series of standard operation procedures or best practices) for a responsible employee health monitoring system. Regarding the former, preliminary findings show that Altairnano's particulate aggregates are of a size that would not likely harm either the environment, employees or consumers.

As for the latter, if this collaboration results in the creation of new best practices for the safe handling and monitoring of nanoparticles, these practices will be broadly disseminated through scientific talks and publications. Hopefully, this collaboration will also serve as a template for similar future efforts within the industry.

Altairnano & University of California-Santa Barbara (UCSB)

We are committed to this explicit goal: There must be little or no direct worker exposure to nanoparticles at the manufacturing site, and there must be virtually no downstream-worker or consumer exposure to free nanoparticles throughout the manufacture, use, and normal disposal of products incorporating these nanomaterials

We will be collaborating with UCSB chemists, and materials, biological and environmental scientists to evaluate the intrinsic health hazard of our materials. Based on the data available in the literature and from our own testing programs, we believe the materials we are using in our products and platforms are generally recognized as safe at normal levels of exposure. Our goal in this collaboration is to learn under what conditions–if any–these materials might pose health or environmental hazards. We will simultaneously be investigating how to modify the composition, surface functionality or morphology of our materials so that they concurrently provide superior performance and inherently low-to-zero health risk.

The Altairnano Lithium-ion battery mentioned earlier is just one of several Altairnano products and initiatives that are "green." The EPA recently suggested six foci for improving environmental sustainability. Our R&D pipeline is already devoted to addressing these four:

- *Sustaining water resources*—Some of our products remove contaminants like arsenic, promote photo-oxidation of microbes and dangerous organics, and inhibit algal growth.
- *Generating clean energy*—We improve the manufacture of high-efficiency photo-voltaics and rechargeable, high-performance "green" batteries.
- *Sustaining clean and healthy air*—Our photocatalytic systems can be added to building HVAC systems.
- *Using materials carefully and shift to environmentally preferable materials*—We're achieving that through development of green products (e.g., Altairnano's innovative Li-ion battery) and manufacturing processes that do not use hazardous solvents.

3. Role of the Federal Government: Ensuring Global Competitiveness of the U.S. Industry

The needs of our society require continued funding to U.S. nanotechnology companies for basic and applied R&D, including priority spending in:

- Alternative energy, for commercially-interesting nano-materials and system solutions to replace or decrease the use of internal combustion engines.
- Life Sciences – For nano-materials and methods to investigate, monitor and treat cancers and cardio-vascular diseases to improve quality of life and decrease the cost of care.

Additionally, the Altairnano safety partnerships outlined earlier are examples of the first step in the type of research still needed to fill in the gaps about nanotechnology. The list of gaps in our knowledge base—connecting characteristics of one type of nanoparticle or another to potential environment, health or safety risks—is very long.

The U.S. is at a critical point in the development of this infant industry. If we go the route of seeking better answers and understanding of the various families/classes of nanomaterials *before* imposing government regulation, it could lead to greater benefits to the consumers and the environment through dramatic changes within widely diverse industries.

Taking the other road—regulation first, without research—could lead to a disquieting moratorium on all future nano-research and development in the U.S., with great cost to our economy. There are some who feel that nanotechnology will require new regulatory legislation – for example, a recent report by Terence Davies with the Woodrow Wilson International Center for Scholars/The Pew Charitable Trusts Project on Emerging Nanotechnologies.

But much of this concern is founded on sparse and sometimes conflicting data. If anything is clear, it is that there is no single prototypical "nanoparticle." Asbestos-like fibrous nanotubes and toxic-metal containing quantum dots are not good surrogates for all nanomaterials. To fall into a "one size fits all" approach to nanotechnology is irresponsible and counter-productive. There are no clear and comprehensive data available to let us really assess the general risk of the wide range of nanomaterials under consideration and/or development.

Many of the cognizant federal funding and regulatory agencies—such as the National Institutes of Health (NIH), the National Cancer Institute (NCI), the Food and Drug Administration, EPA and NIOSH—recognize this reality and are working hard to understand the underlying science and to develop quantitative data and models to quantitatively assess risks.

What Altairnano asks from Congress are the following:

A broad, government-funded initiative (similar to the Human Genome project) with the goal of establishing broad empirical data and models for the predictability of the environment, health and safety risks of commercially-interesting nanomaterials.

Today, we lack data to say what characteristics or properties of a nanomaterial make it potentially harmful. Nor are there sufficient models to predict how the characteristics of materials change upon exposure to the environment, to transport, or bioaccumulation for most of the types of nanomaterials being developed.

While industry, academic, and government scientists continue to vigorously explore nanotechnology's potential *applications* in a wide variety of fields, including ground water cleanup and cancer therapy, research on nanotechnology's potential health and environmental *implications* has failed to keep up. Federal funding for programs to develop appropriate EHS data for use in responsible regulation of nanotechnology is critical. EHS types of R&D comprise less than 4 percent of the core National Nanotechnology Initiative funding for materials and applications R&D. So much more needs to be done.

Federal research dollars are *essential* to supporting the creation of methods and tools critical to developing a fundamental understanding of the risk potential of nanomaterials and nanotechnologies. A metrology and modeling infrastructure would help producers and users of nanomaterials to fulfill their responsibility to identify potential risks of their own materials and applications. With increased federal funding, our society will be in a stronger position to address such risk while these materials are still in an early stage of development and commercialization. An early and open examination of the potential risks of a new product or technology is critical to responsible product development and technology application.

Others have presented the data gaps and modeling needs, and have priced such a program at the $0.5 billion to $1 billion range over the next five to eight years. And, to be very clear, this would not be a program aimed at elucidating the connection of structure-function relationships of certain nanomaterials to performance enhancements in specific applications. Nor should it have a materials discovery thrust.

For a national prioritization of EHS research needs, we need to convene a dialogue of all informed stakeholders to assess what is known, what technologies are available, and what capabilities need to be developed.

Once the needs are prioritized–once we have a roadmap–we can then form teams and consortia, and attack the highest-priority problems. Hopefully a strong federal participation (including staff at NIST, NIH, NCI, EPA, NIOSH, etc.) and substantial federal funding will ensure that what we learn is broadly shared across our entire nanotech enterprise.

Private-sector participation is also critical. But participation by and federal funding to for-profit companies has to be acceptable as a trade-off for their participation, and the sharing of results. Federal investment and participation in developing the underlying EHS metrologies, models and methodologies will dramatically accelerate the realization of the economic potential promised by nanotechnology. This would be an investment that will raise all boats.

I would like to ask you think back just 10 years. Take a minute to revisit the history of the gene chip. In 1994, it was just a dream–a concept that might have utility in clinical diagnostics. The government made a coherent suite of tailored investments in the mid-1990s – less than $200 million of government funding invested in industry-led R&D activities engaging over 100 companies, universities and national laboratories. With the help of that funding, by 2001 we had an infant gene-chip industry, with widespread use in academic and medical research labs and a changing view of what the technology could do. By 2005, gene-chip sales had reached nearly $1 billion and micro-and nano-arrays are now a core tool of modern drug development, as well as powerful diagnostics. Now, health care professionals can't imagine modern medicine without the presence of the gene chip.

This is an excellent example of how the right types of investments at the right time in history can make all the difference. Federal investment into nanotechnology EHS research *today* could lead nano along similar time and economic development trajectories.

Inducements for private-sector companies to engage in that research project, within a framework that is as open and accessible as possible.

Neither academia nor the federal government is going to be able to develop the requisite knowledge base without the help of private industry—especially not without technology start-ups and small materials development companies. Smaller, independent companies like ours are the ones that will ultimately bring the majority of new nanomaterials into the marketplace. These types of companies not only provide insight into the types of materials to which workers, consumers and the environment will soon be exposed, they also provide a window on manufacturing processes and waste streams.

It is in *our nation's* best interest to have them involved, in order to get this right, and to get it right from the start.

To ensure the participation of smaller nanomaterials companies, reimbursement for their participation in such programs is crucial. Unfortunately, most of the NNI funding mentioned earlier goes to federal agencies, like NIH and EPA, which do not generally fund companies. If funding is provided, it's limited to materials-discovery R&D. Even the NIOSH and NIEHS components of the joint STAR grants are limited to the modest funding of $133,000 per year.

Open source infrastructure

Beyond the absence of company participation in most of the current nanomaterials EHS research, there is a fundamental problem with our collective approach to ensuring the responsible development of nanotechnology.

Most large chemical companies involved in nanotechnology have established safety programs and diverse product pipelines. They know what to do, but will wait until specific materials and product concepts have passed through multiple developmental-stage gates prior to undertaking any substantive EHS studies. Even then, the methods used and results will remain proprietary. Because new metrologies and predictive models need to be developed for nanoparticles and materials, this business-as-usual approach is highly inefficient, and will create a few winners and many losers.

What we need are federal R&D programs geared toward bringing companies and academics together to develop a suite of metrology tools and predictive models that will be accessible to and usable by all. This is a critical point in history. Five years ago it was *too early* in the lifecycle of nanotechnology for such a bold plan. Five years from now, it could be *too late* for us to catch up with advances made by competing nations.

Regulatory mentoring

Many smaller nanotechnology companies have no prior experience with worker safety or regulatory compliance programs, and are fearful of "big government's stick." Regulatory agency staffers need to establish informational outreach programs that make it easy to "do it right" from day one. Programs that encourage mentorship from larger, established chemical companies in the same materials or applications space would be especially useful.

Altairnano, and companies like us, need to be able to know that we can approach these federal agencies and get helpful guidance for moving forward. Because we are investing shareholder monies in our R&D and product development programs, we also need to know that evolving regulations will be predictable and based on *sound science* –not political expedience.

One suggestion would be to fund regularly held workshops that gather scientists, technologists and engineers from large and small companies, academic and government research labs, and legal advisors and regulators to discuss application- or materials-specific regulations and appropriate regulatory pathways from product concept to market entry and beyond.

A transparent and consistent regulatory environment that is truly data driven.

I believe we can all agree that there is insufficient quantitative data to inform the development or application of any new regulatory activities. And, anything we attempt to put in place today would likely prove to be an imperfect solution that might be a greater drag on economic development than no regulation at all. There seem to be two common concerns: There is no clear central point of contact and control for nanotechnology, and the number of new materials being developed would swamp the system

I would like to propose a solution that I believe would be embraced by both large and small nanomaterials companies. Let's create a portal to a unified governance committee that operates in a manner analogous to the FDA.

While holding regulatory authority, the FDA is probably one of the single most powerful drivers of economic development throughout the medical industry. The agency staff helps innovators and inventors at early stages of product and process development by teaching them what they need to know and do to comply with the appropriate regulatory framework. The staff provides a way for the innovator's product ideas and work to come up to speed on new technologies as they arise, a single point-of-contact and control, constant and transparent processes, strong outreach and advocacy.

The approval process is also a staged process. For example, in developing a new drug, one might evaluate (at the sub-gram level of manufacture) tens of thousands of molecules before

striking the handful of potential leads that the company considers commercially relevant. It is only at this point that manufacture is scaled up to tens or hundreds of grams and animal trials are undertaken. Only those lead candidates that pass initial animal trials are submitted for limited evaluation for safety (Phase I Clinical Trials).

Essentially, what this means is that only one in many compounds are presented to the FDA for regulatory approval. Clearly, it is at this point that the analogy between development of nanomaterials and therapeutic drugs breaks down. But my point is that there are examples that demonstrate responsible and effective regulatory oversight without imposition of unreasonable burden to the innovators. From a corporate-governance perspective, having an established and rigorous regulatory pathway to market enables innovators to know that they are acting in good faith as product stewards.

Support math and science education at all levels

We all have seen the numbers from the National Science Foundation—while 70,000 Ph.D. engineers are graduating from universities in China and 35,000 from universities in India, there are fewer than 10,000 engineering graduates from universities in the U.S. Plus, many of the U.S. graduates are foreign nationals, many of whom return home with the benefits of their education. This is a national crisis.

For Altairnano, it is also a company crisis. It is extremely difficult for us to recruit science and engineering students from the University of Nevada-Reno. There just are not enough students in the pipeline to go around. Nanotech—the "sexy" science of the 21st Century—might be the catalyst needed to stimulate renewed interest in math and science in American students, from K through graduate school. One approach would be to fund the development of curricula, in coordination with scientists and engineers from local/regional nanotechnology companies, and focused on, perhaps, grades five and six, junior high, and high school.

Another approach could be to fund scholarships to nanoscience camps for students at the junior high and high school levels. A third approach could be to provide scholarships for students enrolling in nanotechnology programs at undergraduate and graduate levels—including curricula focused on nanomaterials and nanochemistry, nanobiology, and nano-environmental engineering. All of these programs should include a component devoted to considerations of public policy issues affecting nanotechnology.

Thank you for the opportunity to speak here today. I will be pleased to try to answer any questions that you might have.

Alan J. Gotcher

Biography

Alan Gotcher is a multi-disciplined business leader with a solid record of accomplishments, bridging unmet market needs with technology based product and service solutions. He led two separate business development teams to create profitable businesses each exceeding $100M in sales and played a critical functional leadership roll in two other business development initiatives.

8/04 – present **Altair Nanotechnologies, Inc.** Reno, NV
President & Chief Executive Officer
A nanotechnology materials company developing performance materials and life science products:

- **Corporate Development:** Conceived, wrote and implemented strategy and business plan for development stage publicly traded company (NASDAQ: ALTI). Company market capitalization increased from <$50M to ~$250 M.
- **Financing:** Raised $20M in cash from 5M share shelf registration.

12/99 – 8/04 **I^{n}Delible Technologies, Inc.** Incline Village, NV
CEO, President & Founder
A technology company developing and providing secure logistic solutions:

- **I^{n}Genius Security Products:** Developed security inks, ribbons and foils to print invisible variable information with off-the-shelf printers as bar codes or marks on products and packaging, which specialized scanners / imagers read and decode for covert security in brand protection.

6/00 – 12/03 **IdeaSpring, LLC** Denver, CO
Co-Managing Director & Co-Founder

- **A Private Investment Firm:** Provided seed round equity investments for early stage start-up companies. Equity investments varied from $250K to $5M. All investments are completed and the fund has closed.

11/84 – 2/98 **Avery Dennison Corporation** Pasadena, CA
Sr. Vice President, Manufacturing & Technology, Chief Technology Officer

- **Manufacturing**: Led $3.5MM company in manufacturing excellence initiatives through 115 manufacturing and distribution sites in 35 countries reducing working capital as a percent of sales from 22% to <8%. Managed $200M annual fresh capital investment in operations.
- **New Business Development:** Led Duracell On-cell tester battery label development program creating a new business with sales >$100M per year.
- **Technology:** Led company-wide product development labs and Corporate Research Center in product and technology development programs that produced 8% organic growth from operations.

Vice President, Corporate Research & Chief Technology Officer

- **New Business Development:** Led USPS self-stick stamp development program that created a business with sales exceeding $100M per year.

1/74 – 10/84 **Raychem Corporation** Menlo Park, CA

- **Laboratory Director, Corporate R&D:** Responsible for the U.S. Corporate Research, leading research & development teams comprising 350 people.
- **Operations Director, PolySwitch® Device Division**: Led the commercialization team for PolySwitch® PTC devices, which was developed into an ongoing business exceeding $100M in sales annually.
- **Group Leader, Corporate R&D:** Led the development of a new class of polymeric PTC over-current protection devices filing >80 U.S. Patents.
- **Research Chemist, Corporate R&D:** Developed a new generation of wire insulation that was specified and purchased by Boeing and Airbus. This wire product family had sales exceeding $100M annually.

EDUCATION: **University of California, Irvine** PhD, Chemistry – 1974 B.S., Chemistry – 1971