

CALIFORNIA COUNCIL ON SCIENCE AND TECHNOLOGY

NANOTECHNOLOGY IN CALIFORNIA

Prepared by the California Council on Science and Technology

For the National Nanotechnology Initiative Review

by the President's Council of Advisors on Science and Technology

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Key Points:

- NNI has been highly influential in California.
- Nanotech is now a significant and increasingly maturing component of the high-tech economy - shifting from an era of discovery to one of commercialization.
- It may be less identifiable as a separate discipline – techniques have been absorbed.
- SMEs dominate commercialization – large industries following.
- California leads nation in health and safety issues - receive much government attention.
- New reporting regulations indicate that well conceived and implemented regulation may bring benefits to industry in the long run but may make firms less willing to participate and report.
- Although a number of California's educational institutions have assumed a leadership role in nanotechnology education and training, workforce production and education remains inadequate to support the industry.

1. Nanotechnology Science and Engineering in California - Brief History

A January 2004 report by the California Council on Science and Technology, *Nanoscience and Nanotechnology, Opportunities and Challenges in California*¹ provided an overview of anticipated economic and societal opportunities offered by nanotechnology. The 2004 report

¹. *Nanoscience and Nanotechnology, Opportunities and Challenges for California; A Briefing by the California Council on Science and Technology for the Joint Committee on Preparing California for the 21st Century*, January 2004, ISBN 1-930117.27-2, <http://www.ccst.us>.

notes, “*What is clear is that nanotechnology is big business. A few nanotechnology-created materials have already entered the consumer market and many more are in the pipeline holding significant promise. Economists predict a trillion dollar global multi-industry market for nanoproducts over the next ten years.*”

The report predicted that nanotechnology industry clusters will form in California around key researcher/entrepreneur networks close to major research universities and predicted an acceleration of global patenting rates of nanotechnology discoveries.

The report also anticipated that in the next one to two decades, new start-up companies will dispassionately compare California’s workforce, policies and business costs with foreign sites when deciding where to base their design and production centers.²

2. California Nanotechnology Industries

According to Lux Research, in its press report dated May 8, 2006, the commercialization of nanotechnology continues to gain speed worldwide. Lux noted that nanotechnology has become pervasive in a wide range of industries, with \$147 billion worth of nano-enabled products, produced in 2007, a figure set to grow to \$3.1 trillion in manufactured goods by 2015.³

However, a more recent (June 2009) report by Lux Research titled *The Recession’s Ripple Effect on Nanotech* cautioned that the current economic downturn has hit key nano-enabled product segments, in particular, in automotive, construction and electronics. Lux predicts that lower output in these three industries will ripple up the value chain to nano-intermediates and nanomaterials. Lux estimates the current market downturn will lead to new estimates of total US revenue of \$254 billion in 2009 from products incorporating nanotechnology, with revised estimates of \$2.5 trillion in 2015 – down 32% and 21% respectively, compared to prior forecasts.

Lux Research further predicts that these current economic changes will put large corporations in the driver’s seat and force start-up companies to improve their bottom lines or close their doors. These challenges will demand creative action from governments.

2. Ibid, Chapter 2, *Information and Transformation of Industries*, by Michael R. Darby and Lynne G. Zucker, University of California, Los Angeles, January 2004, ISBN 1-930117.27-2

3. Press Report, July 22, 2008, Lux Research, *Overhyped Technology Starts to Reach Potential: Nanotech to Impact \$3.1 trillion in Manufactured Goods in 2015*.

In California, the world's sixth largest economy, nanotech has been the focus of much research and technology transfer and industry growth. According to researchers at Georgia Tech, a provisional count of the number of nanotech companies for California from 1990 to 2008 is about 1,400 establishments out of a total of about 5,600 for the US⁴.

Researchers at the NSF and EPA-funded UC Center for Environmental Implications of Nanotechnology at University of California, Los Angeles (UCLA) and the NSF-funded Center for Nanotechnology in Society (CNS) at University of California, Santa Barbara (UCSB) provided for this paper the following observations on the size of the nanotech industry in California. There is some discrepancy with the data from Georgia Tech, which can be interpreted as the difference between data that is cumulative over quite a long haul (GA Tech) vs. a single snapshot (CNS UCSB). For example, the failure rate for start-ups is ~70%.

- In 2006-07, CNS-IRG2 (Interdisciplinary Research Group 2) analyzed about 460 nanoscale *research* grants in California defined through nano* keyword searches in federal and CA state granting agencies. We mapped these in Google Earth, and these maps are still available. Of these 460 grants, 65 were operations in 35 separate companies, all of which were small to medium enterprises (SMEs). This pattern suggests an early-stage science and technology effort rather than a growing industry.
- “Nanotech *industry*” is a different entity. The most complete public listing has been done by the Nano Science and Technology Institute (NSTI) of Cambridge, Mass., a private consultancy and advocacy group. It lists about 430 nanotech companies in California. In 2009, this list has 1,804 companies for the US overall, meaning that California has just under 25% of all US nano companies. (Note data limitations.⁵)
- The National Nanotechnology Infrastructure Network (NNIN) uses the Roco estimate⁶ to suggest that the US might have 900,000 nanotech jobs by 2015. If California retains its 10% share of US manufacturing employment, it would have about 90,000 nano-related

4. Shapira, P., Youtie, J., Kay, L., 2009. *Corporate Entry into Nanotechnology through Patents and Publications: 1990 to 2008*. Atlanta, GA: Georgia Institute of Technology, Program on Nanotechnology Research and Innovation System Assessment (CNS-ASU).

5. Public “nanotech industry” data is not good. The NSTI listing omits at least one promising CA nano-company that we have studied – Nanosolar – and its original list included 30 academic and government laboratories. The NSTI listing also suggests that the US has 3/4ths of total world nanotech employment, which does not correspond with the U.S.’s much lower share of nanoscale research funding, publications, and patents. Most of the firms do not publish workforce data, federal statistics do not break out nanotech as an employment category. Most international estimates are projections for future nano-employment (generally relying on NSF 2001 and Lux 2004 data). We are unable to perform our own count because we cannot afford to subscribe to proprietary firm-by-firm employment data. (This might not be a huge loss, since employment breakdowns via “nano” product lines would still be estimates.) For a similar statement about data limitations, see a European Commission study’s caveat, page 6.

6. Roco, MC, 2002. *Nanotechnology - A frontier for engineering education*, INTERNATIONAL JOURNAL OF ENGINEERING EDUCATION 18 (5):488-497.

jobs by 2015. If California's share of nano-related employment is closer to the share of all industry-filed patents held by California-based companies (about 25%) then California might have as many as 200,000 jobs. Since California nonfarm employment currently stands at somewhat over 14,000,000, nanotech would supply between 0.6% and 1.4% of California nonfarm jobs in 2015 (using the 2010 base). (Note that these figures represent old projections, though they are still in circulation.)

- We offer rough inferential estimates via bracketing based on two census categories incorporating nanoscale research. We are trying to get a *defensible order of magnitude* rather than a solid specific figure.

From 2007 Census data:

- There are 8,079,319 paid employees in 844,552 establishments in sector Professional, scientific, & technical services, or 9.57 employees per firm
 - There are 3,333,390 paid employees in 293,919 establishments in sector Manufacturing, or 45.36 employees per firm
 - Assuming the 430 nanotechnology firms (not including universities) we identified from NSTI follow these trends, then we have between 4115 and 19,504 nano employees in California in 2007 (between 0.02% and 0.14% of total employment).
- CNS suggests that this calculation is “defensible,” and notes by way of comparison that total direct US biotechnology employment – in a far more mature industry – is about 200,000 people, and that California’s share is no more than 50,000.⁷

3. Current and Prospective Applications of Nanomaterials

Examples of commercialization of nanomaterials are concentrated in major industry sectors including, but not limited to:

7. Given the weaknesses in the data, starting with categorization issues, it may be better to raise questions that launch a systematic study, such as:

- 10 years into the NNI, do scientists and businesspeople still feel that nano is emerging as an “enabling platform technology,” for emerging high growth sectors? This is both a technical and a product question.
- Will nano provide lots of middle-class jobs in California and the US, as aerospace did? Or will it follow the Apple strategy in which mass employment in manufacturing occurs elsewhere? In 2000, California still had over 10% of US manufacturing jobs, but has been losing manufacturing jobs ever since. What is it about nanotechnology (or related policy) that might reverse this seemingly entrenched trend? Current data does not allow answers to these questions.

- Agriculture
- Scientific tools
- Electronics
- Military and security
- Environment and energy
- Nanomedicines
- Chemicals and cosmetics
- Materials

Nano-enabled products in today's marketplace, ranging from antimicrobial refrigerators to nano-reformulated drugs, carry a weighted average price premium of 11% when compared to comparable conventional products. Manufacturing and materials applications such as composites and coatings are demonstrating early market entry, but are taking a long time to diffuse. Electronics and IT applications such as advanced memory chips and displays are launching later, but likely to spread rapidly. Healthcare and life science applications such as nanostructured medical devices and nanotherapeutics have the longest time-to-market due to sector-specific regulation.⁸

Nanomaterials include, but are not limited to, nanocomposites, nanocoatings, nanocatalysts, ceramic nanoparticles, metal nanoparticles, carbon nanotubes, fullerenes, dendrimers, nanostructured bulk materials, nanoporous materials, quantum dots, nanowires, nanostructured surfaces, etc.

In November 2002, Dr. Mihail Roco (Senior Advisor for Nanotechnology, National Science Foundation) envisioned four generations of nanotechnology development:

- First Generation: passive nanostructures – 2001 (in coatings, nanoparticles, bulk materials (nanostructured metals, polymers, ceramics))
- Second Generation: active nanostructures – 2005 (such as transistors, amplifiers, actuators, adaptive structures)
- Third Generation: 3D nanosystems – 2010 (with heterogeneous nanocomponents and various assembly techniques)
- Fourth Generation: molecular nanosystems – 2020 (with heterogeneous molecules, based on biomimetics and new design); including technology convergence with large complex systems from the nanoscale resulting in merging of nano-bio-neuro-IT (2015-2020)

The following diagram gives a visual rendering of first and second-generation nanotech applications.

8. Press Report, May 8, 2006, Lux Research, *Nanotechnology in \$32 billion Worth of Products; Global Funding for Nanotech R&D reaches \$9.6 billion.*

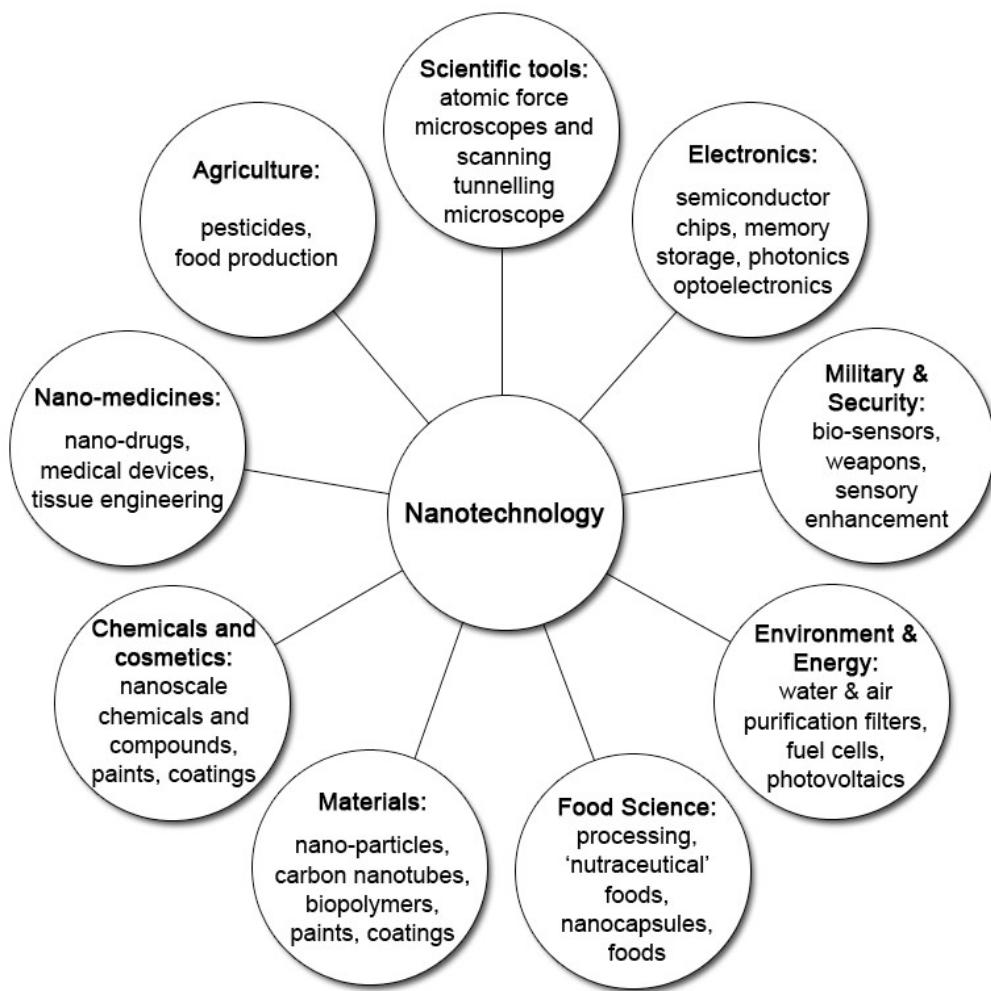


Figure I: Prospective first- and second-generation nanotechnology applications

Source: *Nanomaterials: New Challenges, New Strategies*, Jeffrey Wong, Chief Scientist, Department of Toxic Substances Control, July 29, 2009⁹

4. Role of Research and Development in California

A number of nanotechnology research labs have been created in academic institutions across the state. In addition to research, these research labs provide fee-based user facilities for qualified users, i.e., nanotechnology companies and academic researchers.

9. Chart source: Bowman, Diana M., *Nanotechnology: Mapping the Wild Regulatory Frontier*, Graeme A. Hodge, www.elisever.com/local/futures, 2006.

Examples of California Nanotech Research Institutions include:

Nanoscale Science and Engineering Centers (NSECs) (NSF):

- *Center for Scalable and Integrated Nano-Manufacturing (UCLA)
- *Center for Probing the Nanoscale (Stanford)
- *Center for Integrated Nanomechanical Systems (Berkeley)
- *Center for Nanotechnology in Society (UCSB)--is an NSEC, but listed under networks
- *UC Center for Environmental Implications of Nanotechnology (UCLA, w/ UCSB, UCR, UCD)--not technically an NSEC, but being administered as one.

Materials Research Science & Engineering Center (MRSECs) (NSF) w/ Nano focus:

- * Center for the Science & Engineering of Materials (Caltech)
- * Center on Polymer Interfaces and Macromolecular Assemblies (Stanford)
- * Center for Materials for Information Technology, Materials Research Laboratory (UCSB)

Department of Education Center:

- *Molecular Foundry, Lawrence Berkeley National Lab (enhances capacities for others of the CA NSECs and MRSECs)

Department of Defense Center:

- *Center for Nanoscience Innovation for Defense (UCSB, UCR and UCLA)

National Institutes of Health (NIH) - Nanomedicine Development Centers

- *Center for the Optical Control of Biological Functions (Berkeley)
- * Center for Cell Control (UCLA)
- * Engineering Cellular Control: Synthetic Signaling and Motility Systems (UCSF)

NIH-Centers of Cancer Nanotech Excellence

- * Center of Nanotech for Treatment, Understanding and Monitoring of Cancer (NANO-TUMOR) (UCSD, UCSB)
- * Center for Cancer Nanotech Excellence Focused on Therapy Response (Stanford)
- * Nanosystems Biology Cancer Center (Caltech)

Note: The above list of nanotechnology research laboratories is not complete; there are many other California partners affiliated with these major centers.

Of particular significance (because it was a state initiated program) are the Governor Gray Davis Institutes for Science and Innovation.

In 2000, then Governor Gray Davis established four Institutes for Science and Innovation as research entities focused on priority areas of science and technology in California. Among the four is the California Nanosystems Institute (CNSI), representing a joint venture between the University of California, Los Angeles and the University of California, Santa Barbara.¹⁰

According to the Marketing and Communications Department of the CNSI, the goal of each research center is to encourage university collaboration with industry and to enable the rapid

10. California Nanosystems Institute, <http://cnsi.ucla.edu/>.

commercialization of discoveries. CNSI is comprised of faculty from UCLA, UCSB, and a multi-disciplinary team of investigators in the life and physical sciences, engineering and medicine.

In 2000, California state government pledged \$100 million toward the CNSI to be split between UCLA and UCSB.

The State still contributes annually to the operating budgets of the institutes through the UC budget, allocating \$4.75 million in general funds for operations of the institutes in the 2007-08 budget as part of the Research & Innovation initiative. However, the amount of money the institutes contribute to R&D in the state each year is substantially higher. At the NanoSystems Institute, for example, over 94% of grant funding in FY 2006-07 was derived from federal or industry sources (Table 1).

Table 1: Funding for California NanoSystems Institute at UCLA by source, FY 2006-2007			
	Direct Costs	Facilities & Administrative Costs	Total Awards
Federal Agencies	\$34,430,437	\$13,482,709	\$47,913,146
Industry	\$13,251,977	\$4,358,419	\$17,610,396
Other - Universities	\$1,233,786	\$609,151	\$1,842,937
Other - UC/State	\$1,236,400	\$36,333	\$1,272,733
Foundations	\$317,039	\$27,954	\$344,993
Total	\$50,469,639	\$18,514,566	\$68,984,205

Source: Correspondence with California Nanosystems Institute, 6/16/08

CNSI has developed a research priority in four nanotechnology industry areas in California including:

- Energy
- Environment
- Health – Medicine
- Information Technology

According to CNSI representatives, international linkages have been established through formal collaborations with institutions in China, Japan, Singapore, Korea, the UK and the Netherlands.

To support CNSI research at UCLA, the Institute includes eight core facilities available for faculty use, as well as use by industry and academia. These facilities provide both wet and dry laboratories, equipment such as cryo-electron microscopes, atomic force microscopes, X-ray diffractometers, and robotics for projects led by CNSI and other faculty. Also available to users is the CNSI Integrated Systems Nanofabrication Cleanroom (ISNC) consisting of 8,900 square feet of vertical-flow clean room space including, but not limited to, four class 100 and eight class 1000 clean rooms.

CNSI has also placed a priority on education. Although not a degree-granting entity, CNSI is developing a graduate degree program for students interested in pursuing advanced studies in nanosystems research and technology.

In addition, CNSI at UCLA operates the CNSI High School Nanoscience Program, where graduate students and post-doctoral fellows develop nanoscience experiments that can be used to teach science standards.

A sampling of education programs offered at UC Santa Barbara includes an Apprenticeship Researchers (AR) program for high school juniors and seniors from area schools providing an opportunity for students to conduct research during the summer. UCSB also offers the Burnham Engineering and Applied Science Scholarship Program providing scholarships for incoming UCSB freshmen majoring in Engineering, Mathematics, Physics, Chemistry or Biological Sciences. Both UCLA and UCSB operate outreach programs to area high schools.

Also among the original four Institutes for Science and Innovation created in 2000 is the California Institute for Quantitative Biosciences (QB3), a consortium of three University of California campuses – UC Berkeley, UC Santa Cruz and UC San Francisco, fosters collaborations among scientific researchers to catalyze new discoveries in biosciences through a multi-disciplinary approach including applications and development of nanotechnology (nano/bio).

Status of Technology Transfer

The California Nanosystems Institute (CNSI) is undoubtedly among the best examples in California of a large-scale resource for conducting nanotechnology research and establishing industry partnerships to commercialize nanotechnology innovations.

In particular, small start-up companies in California often do not have access to sophisticated clean rooms and costly instrumentation. According to CNSI, a small firm, i.e., with a developed prototype of a nanotechnology innovation may team with a professor and conduct research and development at CNSI facilities on a fee basis.

The California Nanosystems Institute at UCLA operates a small business incubator program to assist small businesses develop and move their products from the lab to the marketplace. According to CNSI, the small business incubator facility, opened in March 2009, is comprised of

2,000 square feet of flexible lab space to house eight to ten early-stage incubation projects. Clients of the incubator facility are primarily entrepreneurial start-up firms and early stage research projects that originate at UCLA. Users have access to specialized equipment and technical expertise of essential core labs, as well as to faculty and scientists from the schools of engineering, physical and life sciences and medicine.

According to Lux Research, in a 2009 article, *Introducing the Lux Innovation Grid for Nanomaterials*, universities and research labs often use start-up firms to commercialize intellectual property (IP). Technology transfer offices were set up to generate capital from their discoveries through licensing, but in today's market, Lux notes that few corporations and no venture capitalists view licensing as the most advantageous model for commercializing science. The flexibility of small companies addresses the needs of both universities and business, making small firms popular vehicles to push fresh IP out of the labs. To make it easier for decision makers to identify "winning" small firms, Lux Research, Inc. has developed the "Lux Innovation Grid," as a framework for analyzing company performance and evaluating the start-up space overall – both in nanomaterials and other emerging technology areas.

5. California Industry Perspectives

Industry Facilities, Instrumentation and Tools

According to Michael Postek, NIST, in a report titled *Instrumentation and Metrology for Nanotechnology*,¹¹ instrumentation and metrology (the science of measurement) is a key underpinning of the emerging nanotechnology enterprise.

Postek emphasized that advances in nanoscience, and ultimately manufacture of new nanotechnology products will be dependent of the capacity to measure accurately and reproducibly the properties and performance characteristics at the nanoscale. Postek further noted that new nanotechnology-based industries will require high performance, cost effective instrumentation and improved measurement methods.

"As new nanostructures are fabricated, assembled and manufactured into useable products, standardized instrumentation and metrology will be vital for providing quality control and ensuring reproducible performance," Postek added.

Financing Nanotechnology - Venture Capital

According to a recent report by Harris & Harris Group, Inc., Venture Capital for Nanotechnology and Microsystems, Second Quarter Report 2009:¹²

11. Postek, Michael T., National Institute for Standards and Technology (NIST), *Instrumentation and Metrology for Nanotechnology*, Report of the National Nanotechnology Initiative Workshop, Jan. 27 – 29, 2004, Gaithersburg, MD, http://www.nano.gov/NNI_Instrumentation_Metrology_rpt.pdf.

12. Jamison, Douglas W., Wolfe, Daniel B., Janse, Michael A.; Andreev, Alexei A., Harris & Harris Group, Inc., *Venture Capital for Nanotechnology and Microsystems*, Second Quarter Report 2009; August 13, 2009.

....Venture capital in the United States during the second quarter of 2009 was down approximately 37 percent from the second quarter of 2008. The turmoil in the financial markets has affected the values of venture capital-backed companies in merger and acquisition (M&A) transactions. According to data published by Dow Jones VentureSource, the median valuation of venture capital-backed companies sold in M&A transactions during the second quarter of 2009 decreased by 46 percent from the second quarter of 2008.

California is reported as the winner for the highest nanotech venture funding in the country, receiving 41.8% of venture funding to nano firms 1980-2007,¹³ see figure 2.

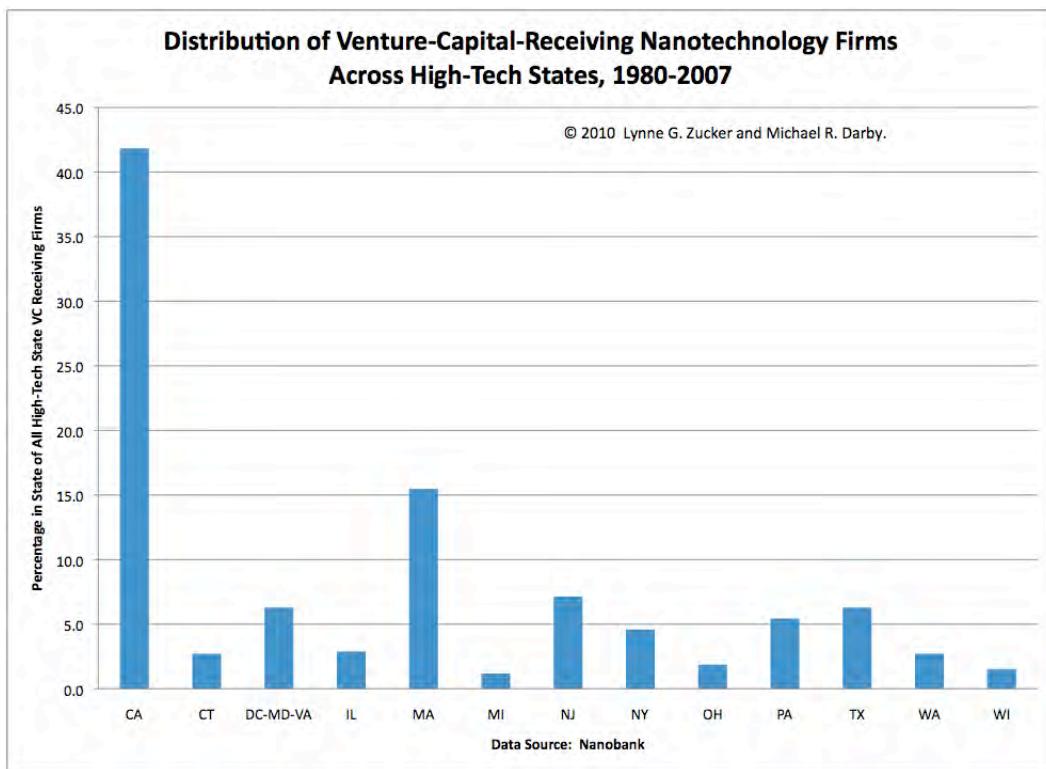


Figure 2: Nanotech Venture Capital

However, the latest National Science Board report *Key Science and Engineering Indicators, 2010 Digest*,¹⁴ shows state-by-state data on venture capital deals as a share of high-technology business establishments as a whole for the years 2003, 2004 and 2006. Findings related to venture capital deals by state conclude that high technology companies in Massachusetts were the most successful in accessing venture capital investment in 2006, with a 2.31% rate. In

13. Communication with Michael Darby and Lynne Zucker, UCLA.

14. *Key Science and Engineering Indicators, National Science Board, 2010 Digest*, National Science Board (NSB 10-02), <http://www.nsf.gov/statistics/seind10/>.

contrast, California companies in high-technology firms obtained venture capital investment at a rate of 1.81%. No other states reached a rate of 1.00%.

Public Sector Funding (i.e. NNI)

The National Nanotechnology Initiative (NNI) is a “virtual” entity consisting of budgets of a cross section of federal agencies that engage in nanotechnology research.

Funding under the NNI is awarded from each individual agency based on an agency’s mission-oriented goals and dollar amounts earmarked and dedicated to nanotechnology.

According to the National Nanotechnology Initiative Coordinating Office (NNICO), the availability of accessible state-by-state grant award data under the NNI is complicated by the multi-agency structure.

H.R. 554, (Title: To Authorize Activities for Support of Nanotechnology Research and Development, and for Other Purposes) contains a provision designed to increase transparency in NNI funding by requiring the National Nanotechnology Initiative Coordinating Office to: 1) develop a database providing information to the public concerning projects funded under the Environmental , Health and Safety, the Education and Societal Dimension, and the Nanomanufacturing program component areas; and 2) develop and publicize information on nanotechnology facilities supported by the states that is accessible for use by individuals from academic institutions to industry.¹⁵

The 2010 budget provides \$1.6 billion for the National Nanotechnology Initiative (NNI), reflecting steady growth in the NNI. The cumulative NNI investment since 2001, including the 2010 request, now totals almost \$12 billion. (Source: NNI funding website at <http://www.nano.gov/html/about/funding.html>.)

*Based on preliminary allocations of the American Recovery and Reinvestment Act of 2009 (P.L. 111-5) appropriations. These figures may change. Other NNI agencies with ARRA funding, but not listed in the table, are in the process of determining their allocations. ¹⁶

6. Research in Monitoring the Industry

It is clear that environmental health and safety and product stewardship practices specific to engineered nanomaterials (ENM) are still being developed. In 2006, an interdisciplinary team at the University of California at Santa Barbara (UCSB), supported by the International Council on Nanotechnology (ICON), surveyed ENM industries worldwide regarding workplace and

15. H.R. 554, reauthorizing activities to support nanotechnology research and development, latest major action: 2/12/2009, referred to US Senate Committee on Commerce, Science and Transportation, <http://www.thomas.gov>

16. Source: NNI funding website at <http://www.nano.gov/html/about/funding.html>.

environmental practices, and product stewardship (Conti et al. 2008¹⁷). Since 2006, the ENM industry has expanded, developed new materials and applications, with likely changing views on risks to environment and health and associated practices. An updated UCSB 2009-2010 study was funded through NSF-EPA (See UC CEIN below.)

The UCSB project seeks to understand the relative influence of industry's views on risk and regulatory guidance on industry risk management practices within the context of uncertain risk. They expect to find strong relationships between industry's views on risk and EHS practices and between concerns for health and for the environment.



First UCSB Industry Study:

- Data collected Summer 2006
- Sponsored by the International Council on Nanotechnology (ICON)
- Public report available at: http://icon.rice.edu/projects.cfm?doc_id=12201

Current UCSB Industry Study:

- Data collected Fall 2009-Winter 2010
- Sponsored by UC CEIN at UCLA and CNS-UCSB

Objectives:

- Update understanding of environmental health and safety practices since 2006
- Expand knowledge of industry's views on risks posed by nanomaterials

Research Questions Include:

- In the context of absent regulation and indeterminate standards, how is industry reportedly adapting their practices for the safe development of nanomaterials? Has this changed over the past three years?
- What determines the extent to which ENM firms follow publicly available guidance documents on nano-specific health and safety practices or respond to toxicity research findings?

Participants are:

- Recruited from North America, Europe and Asia
- From private firms that produce or use nanomaterials

Studies will assess how specific variables, such as risk perceptions and industry characteristics, influence the degree to which industry follows guidance documents. By understanding industry practices and responses to risk, they intend to contribute to knowledge about how best to

17. Conti, J.A., Killpack, K., Gerritzen., G., Huang, L., Mircheva, M., Delmas, M., Harthorn, B.H., Appelbaum, R.P., & Holden, P.A. (2008). *Health and safety practices in the nanomaterials workplace: results from an international survey*. Environmental Science and Technology, 42, 3155-3162.

control environmental risks. This research applies a survey instrument developed through collaboration between social and natural science researchers.

Researchers elicit responses from an international pool of industry participants for a cross-national comparative analysis.

7. California's Regulatory Environment: Mapping the Regulatory Frontier in Nanotech

California state government has actively engaged in raising the awareness of health and environmental issues in nanotech. A brief summary of California legislation impacting nanotechnology within the past few years includes, but is not limited to, the following:

AB 289 (Chapter 699, Statutes of 2006) – Data Call In

- Requires California's chemical manufacturers to provide answers to specific questions about chemicals they make or import into the State.
- Requires specified state agencies to publicly "express interest" in obtaining information about specified chemicals.
- Requires the manufacturer to collaborate and cooperate to the extent practicable.
- Questions may include analytical test methods, fate and transport, and other relevant information.

AB 1879, (Chapter 559, Statutes of 2008) – Safer Alternatives

- Requires the Department of Toxic Substance Control (DTSC), by January 1, 2011, to adopt regulations to establish a process to identify and prioritize chemicals or chemical ingredients in consumer products that may be considered a "chemical of concern" in accordance with a specified review process.
- Creates a prioritization and identification process that includes consideration of specified factors (e.g. chemical volume, exposure potential, potential effects on sensitive subpopulations).
- Requires DTSC, in adopting regulations, to prepare a multimedia life cycle evaluation, as defined, conducted by affected agencies and coordinated by DTSC.
- Requires the evaluation to consider the following impacts: a) emissions of air pollutants; b) contamination of surface and groundwater and soils; c) disposal or use of byproducts and waste materials; d) worker safety and impacts on public health.

(Note: This legislation does not specify applications to nanotechnology, but could be applied to that industry in the future.)

SB 509 (Chapter 560, Statutes of 2008) – Online Toxics Clearinghouse

- Existing federal law requires, under the Federal Toxic Substances Control Act (15 U.S.C., Sections 2601 to 2692, the manufacturer of a chemical to submit specified data to the

US Environmental Protection Agency, including submission of data prior to use in commerce.

- SB 509 requires the Department of Toxic Substances Control (DTSC) to establish a Toxics Information Clearinghouse. The Clearinghouse is a decentralized web-based system for collection, maintenance and distribution of specified chemical information. SB 509 requires DTSC to develop requirements and standards for the clearinghouse and to consult with other states, the federal government and other nations in identification of data for the clearinghouse.

There has not been enough time since enactment of legislation, especially AB 289, to determine if the desired affects have been achieved.

8. State Government Perspectives on Industry Oversight and Societal, Health and Safety Priorities

Health and Safety Issues

Real risks of nanomaterials present challenges due to a lack of data, complexity of the materials, measurement difficulties and undeveloped hazard assessment frameworks. Lux Research noted, in its 2006 report entitled, *Taking Action on Nanotech Environmental, Health and Safety Risks*¹⁸ that, as of 2006, just under 316 peer reviewed journal articles on risks of engineered nanomaterials had been published, giving firms little scientific guidance to go on.

In its 2006 report, Lux Research opined that there are three aspects of the environmental, health and safety issue that firms need to confront:

- Manage real risks of their materials to ensure no actual harm comes to people or the environment;
- Understand perceptual risk, which could undermine public or consumer acceptance of nano-enabled products;
- Understand the emerging regulatory environment.

The 2006 report suggested mitigating real risks would require firms to develop a process plan to:

- Inventory all nanomaterials used across the company;
- Map those materials to applications and, thus, to potential exposures across the product life cycle;
- Characterize the risks of each application based on exposure and available knowledge about the hazard;
- Mitigate risks through exposure controls, additional testing and product redesign.

18. Holman, Michael W., *Taking Action on Nanotech Environmental, Health, and Safety Risks*, Lux Research, June 2006.

Stakeholders generally agree that the potential detrimental effects (both real and perceived) of nanomaterials and devices must be addressed to protect and improve human health, safety and the environment.

California's Global Leadership in Requiring Mandatory Reporting by Nanotechnology Firms

The State of California, through action by the California Legislature and subsequent implementing action by the California Department of Toxic Substances Control, has taken a leadership position in developing a framework for requiring California manufacturers to inventory and report potentially hazardous chemicals, including those developed as nanomaterials.

Specifically, California legislation enacted as Chapter 699, Statutes of 2006 (AB 289, Chan) authorizes a state agency (as defined) to request a manufacturer of a chemical to provide the state agency with specified information regarding the chemical. An authorized state agency request includes, but is not limited to, an analytical test method for that chemical in a specified material and other information relevant to the fate and transport of the chemical into the environment.

As a result of AB 289, the California Department of Toxic Substances Control (DTSC) has launched the **California Nanotechnology Initiative** as a regulatory initiative allowing the Department to request a California manufacturer of nanomaterials to provide specific baseline information required for review and assessment of the nanomaterial relevant to issues such as potential hazardous chemical content, health and safety processes and procedures in the workplace, and fate and transport of the material into the environment. The DTSC focus is on emerging contaminants.

DTSC is interested in nanotechnology because:

“...the department sees nanotechnology as the new “plastic” because it will show up in many industrial applications and consumer products. Materials and devices designed at the nanoscale level are being used or considered for use in applications as diverse as cancer treatment to scratch-resistant automotive coatings. Because of the unique properties of nanomaterials, DTSC is gathering information on nanotechnology and monitoring the efforts of other regulatory agencies about this emerging technology.”¹⁹

DTSC confirms there is currently no routine methodology or protocol to detect, sample or measure nanomaterials. According to the DTSC, as a result of its California Nanotechnology Initiative, California has the only mandatory reporting requirement in the world.

19. California Department of Toxic Substances Control, *Why is DTSC interested in nanotechnology?*” <http://www.dtsc.ca.gov/Technology Development/Nanotechnology/index.cfm>.

In implementing the Department's California Nanotechnology Initiative, a “**Chemical Information Call-In**”²⁰ has been implemented in which the Department contacts the California manufacturer with a series of questions relating to:

- The source of the manufacturing of the nanomaterial and a description of the end user(s);
- Measurement and detection procedures used;
- An assessment of the manufacturer’s knowledge about the material and its potential impact on the environment;
- Occupational safety assessment of the nanomaterial;
- Current workplace protection measures deployed;
- Inquiry regarding whether the material is hazardous based on the federal Resource, Conservation and Recovery Act (RCRA).²¹

The Department's California Nanotechnology Initiative is a public/private sector collaborative process consisting of the following steps:

1. Identify California manufacturers and information needs for each chemical;
2. Search state, federal and intergovernmental databases;
3. Build a bibliographic database of the information gathered;
4. Consult with external experts on information needs (universities, industry associations and others);
5. Consult with manufacturers;
6. Post the information request on the DTSC and Cal/EPA websites;
7. Make a formal request for information;
8. Collaborate with manufacturers to identify additional information needed;
9. Allow manufacturers up to one year to provide the requested information;
10. Protect trade secret claims;
11. Organize information as it is received;
12. Evaluate/Request additional information, if needed;
13. Share the information.

The DTSC has developed a timeline and schedule of focus on various categories of nanomaterials based on determinations as follows:

20. California Department of Toxic Substances Control, Chemical Information Call-in: Nanomaterials; Ibid.

21. The Resource, Conservation and Recovery Act (RCRA), enacted in 1976, is the principal Federal law in the United States governing the disposal of solid waste and hazardous waste. Congress enacted RCRA to address the increasing problems the nation faced from its growing volume of municipal and industrial waste. While RCRA handles many regulatory functions of hazardous and non-hazardous waste, arguably its most notable provisions regard the “Subtitle C program,” tracing the progress of hazardous wastes from their point of generation, their transport, and their treatment and/or disposal. This process has become known as the “cradle to grave” provision of the law.

- Some indication of toxicity exists;
- The material has widespread deployment;
- The fate and transport of the material is unknown.

The DTSC current conceptual schedule of inquiry is as follows:

- Carbon Nanotubes (current request to California manufacturers is due by end of January, 2010)
- Nano Silver (2010)
- Reactive Nanometals (2010-2012)
- Dendrimers (2013)
- Quantum Dots (2013)

Note: The above schedule is tentative and not incorporated in official DTSC policy at this time.

Although AB 289 contains no explicit penalty in law for non-compliance, the DTSC will defer to the Attorney General if a manufacturer fails to respond to an inquiry within 365 days. Non-compliant manufacturers will be identified on the DTSC website.

Both California manufacturers and research institutions are subject to DTSC reporting requirements under the DTSC California Initiative. According to Dr. Jeffrey Wong, Deputy Director, DTSC, reporting safety protocols for research institutions are currently being developed in partnership with University of California, Los Angeles, University of California, Santa Barbara, University of California, Riverside, and Stanford University.

According to Dr. Jeffrey Wong, the Department's goals for the California Nanotechnology Initiative are to provide information to the marketplace reflecting company and vendor knowledge, and gather factual information regarding nanomaterials. Providing evidence from California nanotechnology industries concerning what is needed to protect workers in the workplace and assess environmental impacts will provide a basis to pursue future federal funding through the National Institute for Standards and Technology (NIST) and the National Institute for Occupational Safety and Health (NIOSH).

The Center for Nanotechnology in Society at UCSB reports that national survey data from 2008 indicates well conceived and implemented regulation may bring benefits to industry in the long run.

Will California's mandatory reporting process for nanotechnology products and materials now being initiated at the Department of Toxic Substances Control be duplicated at the federal level or elsewhere?

According to the Fall 2009 Nanotechnology Law Report²² “Eight months after the US EPA’s interim report on industry participation in its Nanoscale Materials Stewardship Program, EPA’s Toxic Substance Control Act (TSCA) Interagency Testing Committee (ITC) recently published a report in the Federal Register noting that EPA may issue a new mandatory data collection rule for nanomaterials under TSCA Section 8 (a):

EPA intends to develop a proposed TSCA Section 8 (a) rule to obtain information on the production, uses, and exposures of existing nanoscale materials...

EPA also intends to develop a proposed TSCA Section 4 rule to develop needed environmental, health and safety data.”

It should be noted that the Center for Environmental Implications of Nanotechnology (CEIN) located at the University of California, Los Angeles within the California Nanosystems Institute at UCLA (See Section 7 above), has plans for industry education and partnerships with California industry to assist in responding to the current demand for data on toxicological and ecological risks of nanotechnology.

9. 21st Century Workforce Training Needs – Are We Keeping Up?

In November 2002, Dr. Mihail C. Roco, Senior Advisor for Nanotechnology, National Science Foundation, predicted that nanotechnology would generate a new world of products valued at approximately \$1 trillion per year in 2010 – 2015 in major industry areas including materials beyond chemistry, electronics, pharmaceuticals, chemical plants, aerospace and tools. He predicted this industry growth would require 2 million nanotech workers worldwide.

In California, according to a 2006 report by the California Community Colleges, *Training California’s New Workforce for 21st Century Nanotechnology, MEMS, and Advanced Manufacturing Jobs*²³ predicted 226,800 new nanotechnology jobs would be created in California as a result of nanotechnology industry growth. The 2006 report noted the challenge will not only be in workforce training needed to fill job openings created by retiring, highly skilled workers, but also to retrain incumbent workers in the technical requirements of these new enabling technologies.

In May 2009, Dr. Stephen J. Fonash, NSF National Nanotechnology Applications and Career Knowledge Center, Penn State University, noted:

22. *EPA May Issue Mandatory Data Collection Rule for Nanoscale Materials Under TSCA*, Nanotechnology Law Report, Fall 2009.

23. Koehler, Gus, *Training California’s New Workforce for 21st Century Nanotechnology, MEMS, and Advanced Manufacturing Jobs*, for California Community Colleges Workplace Learning Initiative, 2006.

“Today a country’s economic viability and its citizens’ job mobility require that its workforce have a strong micro- and nanotechnology education providing a skill set covering synthesis, fabrication and characterization.”

Examples of nanotechnology workforce training programs in California include the following:

California Community Colleges

Although no statewide nanotechnology workforce-training program exists at the California Community Colleges, several community colleges have developed local nanotechnology education and training programs. One example is Foothill College. According to faculty member Robert D. Cormia who heads Foothill’s program, Foothill has recently been awarded a National Sciences Foundation grant for nanomaterials and engineering.

In Fall 2010, Foothill College will launch an Associate of Science (AS) degree in Nanoscience Technology. Students will study three quarters per year plus summer programs and in the final year will complete a three-month internship with a local high technology manufacturing firm. Graduates of this program will be equipped to work as a technician in support of scientific research and development. For those seeking higher education, Foothill has partnered with UC Santa Cruz as a transfer opportunity to UCSC’s four-year degree program in nanoelectronics. Foothill College also offers a certificate program in nanotechnology.

Other California community colleges offering nanotechnology courses include, but are not limited to the following:

- San Jose Evergreen Community College District – As a result of an award of \$300,000 from the State Chancellor’s office of the California Community Colleges, San Jose Evergreen Institute for Business Performance offers nanotechnology training to California businesses.
- College of the Canyons – In November 2009, the College of the Canyons announced a new state of the art cleanroom facility to train students in pursuing careers in the sciences, including nanoscience and nanotechnology.²⁴
- Ventura College/College of the Canyons/Santa Barbara City College/ University of California, Santa Barbara: Two-year certification program in nanotechnology.

A proposal has been submitted to NSF to establish a two-track, 2-year nanoscience/technology educational program for community college students. This project will involve collaboration

24. Press report, *Cleanroom Facility Unveiled at College of the Canyons*, KHTS Hometown Station AM 1220, Santa Clarita Radio, November 20, 2009, <http://hometownstation.com>.

between Ventura College, College of the Canyons, Santa Barbara City College and University of California, Santa Barbara (Status: Pending NSF Review and Funding)²⁵

International Association of Nanotechnology (IANANO)

The International Association of Nanotechnology (www.ianano.org) based in San Jose, California, following a \$1.5 million award under the President's High Growth Job Training Initiative, offers workforce preparation programs in nanotechnology through IANANO's California Institute of Nanotechnology (CINT). This includes professional training designed for business executives seeking nanotechnology skills. The CINT also offers 8-week certificate programs under the title of Certified Nanotechnology and Clean Technology Professionals as well as Apprenticeships in Nanotech and Clean Tech – Paid on the Job Training.²⁶

Nano High – Lawrence Berkeley National Laboratory (LBNL)

The Material Sciences Division of LBNL operates "Nano High," a series of free Saturday morning lectures by Berkeley professors and LBNL senior scientists conducting research on topics from nanoscience to molecular medicine, and climate change to astrophysics. 2009-2010 will be the seventh year of operation of Nano High. Nano High talks are aimed at all high school students, including those committed to science career as well as those still exploring their chosen field. (<http://www.lbl.gov/msd/nanohigh/>)

University of California at Berkeley

Although UC Berkeley does not award science and engineering degrees that carry the names "micro" or "nano", micro and nanotechnology permeate the campus.²⁷ UC Berkeley's research and education priorities have grown so rapidly that the university has created an umbrella organization referred to as the Berkeley Nanosciences and Engineering Institute, to coordinate programs. More than 80 faculty members in biology, chemistry, computer science, earth science, engineering, materials science and physics are Institute members.

The samplings of nanotechnology education and training programs listed above are examples of California's educational institutions that have assumed a leadership role in nanotechnology education and training.

25. NanoEd Resource Portal, A Repository for the collection and dissemination of information for the NSEE community, Program: 2 year A.A. Certification in Nanoscience Technology: Ventura Community College, College of the Canyons, Santa Barbara City College, University of California, Santa Barbara.

http://www.nanoed.org/degree/degree_associate/.

26. Source: California Institute of Nanotechnology, <http://www.ianano.org/site/training/index.html>.

27. Small Times Magazine, May/June 2007 issue, highlighting a complete listing of universities participating in a Small Times Survey on micro and nanotech resources;

http://www.smalltimes.com/document_display.cfm?document_id=11552.

However, according to a report released in Fall 2009 by the Center for the Future of Teaching and Learning, *The Status of the Teaching Profession 2009*,²⁸ the supply of college-educated workers in California has not kept up with demand, and projections show the state will suffer a serious shortfall of college graduates by 2025 if current trends continue.

10. Recent Report Recommendations Supporting Nanotechnology Industry Development in California

California Council on Science and Technology

Nanoscience and Nanotechnology: Opportunities and Challenges In California, A Briefing for the Joint Committee on Preparing California for the 21st Century, January 2004.

28 . *Teaching and California's Future, The Status of the Teaching Profession 2009*, The Center for the Future of Teaching and Learning in partnership with California State University, University of California, Office of the President, and West Ed (Research conducted by SRI International).

CCST Report to the Joint Committee on Preparing California for the 21st Century
[\(http://www.ccst.us/publications/2004/2004Nano.php\)](http://www.ccst.us/publications/2004/2004Nano.php)

Challenges to the healthy development of California's nanotechnology industries include the following:

- *Loss of Existing Assets* -- the loss or degradation of any of California's existing high-tech assets -- such as our skilled workforce, concentration of venture capital, strong research institutions -- would be extremely problematic.
- *Scope* -- though we often think of nanotechnology as a singular field, it actually represents a collective advance across several disciplines. Development will certainly not be uniform, and there is the potential that public concern about implausible applications may halt research across the board.
- *Transition* -- existing industries will have to undergo radical transformation to survive such changes as the shift from silicon-based computer chips to carbon nanotube-based chips.
- *Intellectual Property (IP)* -- nanotechnology will lead inefficiencies and us to uncharted legal territory (can you patent an atom?) and inefficiencies in the transfer of IP between universities, government and industry could dampen business activity.
- *Environmental and Social Impacts* – although the commercial synthesis of nanomaterials has begun, we have few data on the impact large quantities of these materials will have on the environment or on human health.

Among the report's many recommendations to the Governor and Legislature:

- *Education* -- because California's workforce has always been our surest source of competitive advantage, and therefore a major factor in business attraction, invest in education and workforce training.
- *Economic policy* -- re-engineer state tax incentives to address the needs of these emerging industries, examine siting for nanomanufacturing in California, and facilitate commercialization by encouraging close ties between industry and the academe.
- *Social and Environmental Issues* -- many of the environmental and social implications of nanoproducts and processes are unknown. Establish nanoethics centers in higher education and multi-agency government teams to identify essential health, environmental, and other impacts.

[Thinking Big About Thinking Small An Action Agenda for California](#) Blue Ribbon Task Force on Nanotech, December 2005, US Rep. Mike Honda (D-San Jose) and California State Controller Steve Westly (D).

Similar recommendations adding:

- Bridge innovation/commercialization gap
- Promote and mark nanotechnology assets
- Launch "California Innovation Initiative"
- Take steps to ensure that education systems are adequate

11. Impact of NNI in California – Industry Perspective

According to researchers and industries in California (although not a systematic study) indicate that the National Nanotechnology Initiative (NNI) has been a great success through its funding of fundamental research, as well as catalyzing a productive cycle of innovation manifested in corporate R&D and venture capital. According to Lux Research, Inc. tens of billions of dollars worth of products now incorporate nanotech and other countries are eroding the US's dominant position. In its policy article titled *Change Required for the National Nanotechnology Initiative*,²⁹ Lux noted as NNI is reauthorized, its focus should shift to application development, manufacturing scale-up, and its approach to environmental, health and safety issues (EHS) must be overhauled.

As noted based on discussions with representatives of industry, there is general concern over whether the evolution of understanding of, and response to, health and safety issues is effectively penetrating in all industry places where nanotechnology is being developed. As noted by the California Nanotechnology Industries Network, in large companies a greater understanding of health and safety issues is emerging. Factors include improved access to nanotechnology instrumentation, facilitating detection and measurement, access of clean room facilities and strong information networks. Those same resources and knowledge are often less available to small firms.

Lux Research, in a December 2004 article, *Benchmarking US States for Economic Development from Nanotechnology* identified California as one of nine states categorized as "Nano-Leaders" due to a high level of activity in nanotechnology and general technology development strength.

A *New York Times* article, *Collaborating for Profits in Nanotechnology*(July 15, 2009),notes that although the economic news in California has been bleak, with political wrangling over a multi-billion dollar budget deficit and budget cuts pending for the state's world-class higher education sector, there remains a promise for the future in collaboration by California's university research centers, small companies and venture finance firms in the emerging area of nanotechnology. The *Times* article emphasized California's universities have been essential in this development process – in some cases making direct equity investments in start-up companies – often considered key drivers of innovation in today's marketplace. In other cases, universities grant licenses to their research and give small firms access to expensive laboratory equipment in exchange for user fees.

Dr. Leonard H. Rome, associate director of the California NanoSystems Institute at the University of California, Los Angeles emphasized that partnerships with private industry are a way of making this new technology available for public benefit. Partnerships also bring needed

29. Nordan, Matthew, President, Lux Research, Inc., April 24, 2008, *Change Required for the National Nanotechnology Initiative as Commercialization Eclipses Discovery*.

funds, i.e. allowing the California NanoSystems Institute to attract more than \$850 million in research and development funding from federal and industry grants. . To capitalize on California's leadership in nanotechnology development, note should be taken of the observation by Lux Research that in the last seven years, emerging nanotechnology has increasingly become a fact of life and of business, as the technology has shifted from an era of discovery to one of commercialization.³⁰

An analysis of best practices in nanotechnology commercialization, *Nanotechnology Commercialization Best Practices* (Waitz/Bokhari) noted, "...most commercialization efforts start with taking steps to protect IP through the filing of patents. Most patents in the area of nanotech are generated by either large companies, or by universities or government labs."

California is in a promising position to maintain and advance its global leadership in nanotechnology based on the linkages it has forged between its world class universities and small firms – commonly referred to as "engines of innovation."

12. Conclusions

Lux Research predicts, in its 2009 report, *The Recession's Ripple Effect on Nanotech*, that although the current recession may end in a year or two, its impact on nanotechnology industries will remain. Due to long replacement cycles and lengthy design-in times in automotive and construction, Lux predicts nanotechnology industries will be feeling "aftershocks" well into the next decade.³¹

California's competitive advantage rests in the collaboration by California's university research centers, small companies and venture capital firms in capturing economic and societal benefits of nanotechnology in the 21st century. The EHS concerns are being addressed, but the results of state government intervention are not known at this point.

Leadership in workforce preparation and active support and participation by government will also be critical to ensure a competitive environment for nanotechnology industries to flourish, while improving worker protection, state-of-the-art practices in health and safety and environmental protection.

30. Ibid.

31. Breadley, Jurron, Ph.D., *The Recession's Ripple Effect on Nanotech*, Lux Research, Inc., June 2009.