

November, 2010

Dear members of the Wisconsin Legislature's Special Committee on Nanotechnology:

Thank you for participating on this important committee. I am writing to respond to the letter submitted by Dr. Dietram Scheufele on Sept. 25, 2010. Before responding to his specific points, I'd like to share a bit about my background and my work, some of which led to the existence of this committee.

My background

I received my Masters in environmental studies (2000) and PhD (2004) in environmental studies and journalism/mass communication (joint degree) at from UW-Madison Gaylord Nelson Institute for Environmental Studies. My work focused on the health risks and communication disparities related to the consumption of potentially contaminated Great Lakes fish, especially by lower income and minority subsistence anglers. During graduate school at UW-Madison, I taught biology, environmental studies, ecological conservation, communication and four semesters of environmental policy.

Also, for the last 20 years, I have engaged extensively with a variety of community groups in several cities, in collaboration with local and state government agencies on numerous local, state, and national environmental health issues. I have served on several non-profit boards working on climate change, ecological conservation, water quality, air quality, and environmental justice.

After finishing my doctorate in 2004, I took a National Science Foundation-funded postdoctoral position with the UW Nanoscale Science and Engineering Center (NSEC). I eventually became a research scientist and the co-leader of the societal implications team for the center. I recruited several UW research scientists with expertise in toxicology and environmental fate and transport (including Dr. Dick Peterson, who is on this committee), to join the team to create a multi-disciplinary approach to proactively addressing nanotechnology environmental health and safety issues.

In 2005, I created and led a collaborative, multi-disciplinary working group of government agency scientists called the "Intergovernmental Nanotechnology Working Group" (IGNG). I am still engaged in projects with some members of this team. The IGNG eventually grew to include scientists from the Wisconsin Department of Natural Resources, the Wisconsin Dept. of Health Services, the Wisconsin State Lab of Hygiene, the Dane County Local Emergency Planning Committee, Public Health Madison Dane County, and external members from the Minnesota Pollution Control Agency, the National Institute of Occupational Safety and Health, and the United States Geological Survey. It also included one of the leaders of the UW Advanced Materials Industrial Consortium. This team, consisting mostly of PhD level scientists, met monthly from 2005-2009 to discuss nanotechnologies and outline what scientists and staff in their agencies, and companies, would need to know to prevent potential public and environmental health problems related to emerging nanotechnologies (see: <http://www.nsec.wisc.edu/NS--Nugget.php?ID=42>). In 2007 I co-organized the highly successful Midwest NanoSafety Workshop with some members of this group, safety personnel at other

Midwest universities, and leaders from NIOSH—see:
<http://www2.fpm.wisc.edu/safety/nano/index.htm>.

Members of the IGNG also worked closely with Rep. Terese Berceau beginning in about 2006 on developing the Wisconsin nanomaterial registry concept, which they felt would be very beneficial in protecting public, worker and environmental health. We worked together for years to build the impetus that led to this committee's formation.

During my time with the NSEC, I also co-organized numerous citizen engagement projects, including the 2005 Citizens Consensus conference (<http://www.nsec.wisc.edu/NS--Nugget.php?ID=3>), the Madison Nano Cafes (http://www.nanoceo.net/past_events#Nano-Cafes-Concept), and much more. Working closely with an organized lay citizen group, I have actively engaged hundreds of Wisconsin citizens in discussions with scientists on nanotechnology issues they were interested in—see: http://www.nanoceo.net/past_events. Eventually, out of these efforts, the Nanotechnology Citizen Engagement Organization (NanoCEO) was formed, a non-profit organization that is now independent of the UW—see <http://www.nanoceo.net/about>.

I have published numerous research papers in peer-reviewed journals, including articles about nanotechnology environmental health and safety issues, workplace exposure monitoring, citizen engagement in nanotechnology, nanotechnology risk policy, and environmental justice. From 2007-2009, I served on several nanotechnology policy advisory boards and/or working groups. I was on the science advisory panel for the UC-San Francisco's "Nanotechnology Policy Framework for California" and a working group member of the University of Minnesota's "NIRT: Evaluating Oversight Models for Active Nanostructures and Nanosystems: Learning from Past Technologies in a Societal Context." I will serve on the science advisory panel for the EPA's Nanoscale Silver Case Study in January 2011.

I worked for the NSEC through 2009 when I moved on to become a community-based researcher with NanoCEO. Dr. Scheufele and his colleagues, who are public opinion and strategic communication and marketing research experts, replaced me in the NSEC in 2009.

Inaccurate and/or misleading points in Dr. Scheufele's Sept. 25 letter:

To adequately fulfill its mission and make informed, innovative, effective policies for Wisconsin, the committee should have accurate information about what has happened regarding nanotechnology environmental health and safety policies to date. In that light, I would like to point out the incorrect information in the letter submitted to this committee by Dr. Dietram Scheufele on Sept. 25.

1. The Sept. 25th letter notes that "local municipalities, such as Cambridge, MA and Berkeley CA, have pondered or implemented similar regulations and reporting requirements in the past. Interestingly, neither California nor Massachusetts has engaged in any statewide efforts to adopt these local guidelines."

This statement is misleading and reflects a significant misunderstanding of what is happening in these communities and states regarding nanotechnology policy development. I and others on the

IGNG have talked many times with those who initiated efforts in Cambridge, Berkeley, and California, who are mostly high-level agency scientists committed to protecting public, worker, and/or environmental health. I continue to engage regularly with the scientists at the California Dept of Toxic Substances Control (DTSC), who developed that state's nanomaterial call-in program—see: <http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/index.cfm> and more specifics here: http://www.dtsc.ca.gov/PollutionPrevention/Chemical_Call_In.cfm. This innovative program was developed in cooperation with a wide range of experts and institutions, including scientists from other agencies, industry, NGOs, and the U.S. EPA.

Both the Berkeley and CA DTSC efforts were based in part on authorities these agencies have from *existing state and federal laws*. The CA DTSC developed its call-in program based on Assembly Bill (AB) 289 which gave them authority to gather certain kinds of information under the *Health and Safety Code* Section 57019 (which does not focus on nanomaterials per se). The DTSC call-in program is a unique and creative collaborative strategy for generating the information the DTSC scientists have decided they need to protect public and environmental health. It is mandatory but also flexible and able to integrate new information and developments. Rather than targeting all engineered nanomaterials (which doesn't make sense), it prioritizes only those engineered nanomaterials (and other chemicals) that scientific research suggests may be harmful to humans and/or the environment, and then adds new nanomaterials to the list as new scientific research comes out and based on discussions and meetings with diverse collaborators. It is reflexive and transparent, involves accessible public information, public forums, and engagement with nano companies to help them understand how to comply and provides resources for doing so. The program isn't perfect; it is facing many challenges in its first couple years, but it is a great start and they are learning and improving it as they go.

The Berkeley ordinance, developed by scientists at the City of Berkeley's Toxics Management Division, was also based on using existing *federal law* (SARA Title 3, otherwise known as Emergency Planning & Community Right to Know Act, EPCRA), state law (the California Health & Safety Code) and other existing laws and risk management programs in Berkeley and California. As with the California call-in program, creating this involved innovative policymaking, and at the same time did not re-invent the wheel (by utilizing existing laws).

Several of these existing laws discussed above were posted on the special nano committee website on Sept. 16: <http://legis.wisconsin.gov/lc/committees/study/2010/NANO/index.html>.

2. The Sept. 25th letter goes on to note that "...there are good reasons" that the states of MA and CA have not implemented reporting requirements, describing the "vibrant innovation clusters for emerging technologies, such as nanotechnology" in these states.

The first statement, of course, is incorrect in the case of California (as described above—I will not elaborate on MA here for lack of space). Moreover, the intended message here is that reporting requirements will drive nanotech research and development out of the state. **This familiar argument is a red herring**—one often used by those opposed to environmental health and safety regulations or even simple reporting requirements.

Yet there is no evidence suggesting that policy developments in California or Massachusetts are driving nanotechnology research and developments out of these states. In fact, the letter itself refutes this argument explicitly, noting that there are “vibrant innovation clusters” in California and that the University of California system is a clear leader in the September 2010 ranking of U.S. universities based on the number of nano patents they have filed. Apparently, the existing reporting requirements in California, not to mention other existing and proposed progressive environmental and health policies in CA, have not dampened research or innovation in the state, as the letter implies they will. Nanotechnology and other technological research and developments in Cambridge and the state of Massachusetts, moreover, are also thriving.

3. The Sept. 25th letter notes that “our most recent nationally representative survey of the leading nano experts in the U.S. showed that they see the highest likelihood for success in national and international regulations rather than local guidelines. This expert assessment is very much in line with the views of many policy makers who have expressed grave concerns about reporting requirements, similar to the ones by the City of Berkeley that create an unrealistic administrative burden for academic and commercial labs, and have pushed investors to other areas of the country.”

These survey results are not surprising and it is not clear why they are relevant to this discussion. I have read Dr. Scheufele’s study and it does not clarify who these scientists are (what specific backgrounds), but I assume most were engineers, physicists, chemists, biochemists, etc., who are creating or studying nanomaterials in their labs. I have also interviewed numerous nanotechnology research scientists at UW and at other universities, and not surprisingly, few to none have any background in environmental/health regulation or risk policy. Many are not familiar with even the most basic laws, regulatory structures or agencies in their communities, states, or at the federal or international levels. While many lab researchers take lab safety seriously and use adequate safety protocols in their labs, a disturbing proportion of them do not (which I know first-hand having worked in research labs and worked with EHS personnel at UW and elsewhere).

It is also hardly surprising that research scientists might be resistant to reporting what they are making in their labs. I suspect this resistance is not necessarily because it would entail “unrealistic administrative burdens” (although this may be part of the reason), but more likely, the resistance to disclosure among lab scientists has more to do with issues related to research competition, accountability, and in some cases resistance to addressing lab safety issues. Regardless of the reasons, I find it questionable that reporting requirements considered or implemented by others are “unrealistic” and “have pushed investors to other areas of the country.” Have researchers, companies, and investors really moved to other states and countries because they had to fill out some extra forms, perhaps once a year or even less?

The letter does not say who the policymakers are that have expressed “grave concerns” about reporting requirements, nor what these “grave concerns” are. Regardless, in response to these comments, I would like to highlight that, as described above, in the case of Berkeley, Cambridge, and the California DTSC, it was primarily **scientists, policymakers, and government agency staff who initiated efforts to develop reporting requirements—often in collaboration with industry**, because they, like members of our intergovernmental nanotechnology working group,

believe that having this basic information is an essential first step for them to do their jobs protecting worker, public, and environmental health. So clearly, some scientists and policymakers, including leaders in local, state and federal agencies think local and state disclosure requirements are a good idea and moreover, that they are realistic and doable. Further, these scientists and policymakers apparently are not “gravely concerned” about driving research and industry out of their states, which makes sense given that their states continue to have thriving technology research and development sectors.

Finally, I would like to note here that regardless of the rationales, “unrealistic administrative burdens” are not adequate or defensible reasons not to develop reporting requirements that would help government agencies better protect worker, public, and environmental health.

4. The letter attempts to argue that the U.S. federal government is adequately addressing environmental health and safety issues related to emerging nanotechnologies, by noting that the NNCO “will soon release a report with concrete recommendations for national and international regulatory frameworks” and “most federal agencies have already increased their focus on issues related to environmental health and safety aspects of nanomaterials.”

Unfortunately, these vague statements do not support the argument that the federal government is adequately addressing nanotechnology environmental health and safety issues or that it will any time soon. The National Nanotechnology Coordination Office (NNCO) has no regulatory authority nor is it charged with formal risk assessments or developing policy (it is a “*coordinating* office”). Given this, the fact that the NNCO “will soon release a report” with “recommendations” is somewhat meaningless. The assertion that unnamed federal agencies have “already increased their focus” on environmental health and safety aspects of nanomaterials is equally meaningless. Neither of these claims support the statement that the federal government and/or the NNCO in particular is “dealing with environmental and health impacts of nanomaterials, as well as ethical, legal, and other societal issues” as the letter purports.

Further, even if government entities will “soon release reports,” this will do nothing to provide information about where, how much, and what types of engineered nanomaterials are being created to scientists, risk assessors and others who need this information—one of the main purposes of reporting and disclosure requirements. Reports do nothing in themselves, and in some cases they prevent anything from being done by giving the false impression that something is being done. Moreover, hundreds of reports (see some of them here: <http://www.nanoceo.net/regulatory-issues--scroll> down to “reports”) have been published throughout the world in the last decade on how to address potential environmental health and safety risks of nanotechnologies. These reports, while containing useful information, are doing little in themselves to protect worker or public health or to provide concrete information risk assessors need. **This is why scientists and risk assessors in agencies and governments all over the country and the world are calling for nanomaterial inventories, registries, or other monitoring strategies as soon as possible so they can begin to take concrete actions to protect people and the environment when appropriate.**

While perhaps it could have been argued in the early 2000s that federal level agencies were staying on top of environmental health and safety issues related to nanotechnologies (and even

then analysts were questioning this), this is clearly not the case now. Even federal level agency leaders and policymakers are admitting that it is becoming increasingly difficult to keep up with nanotechnology developments as thousands of industrial and consumer products with engineered nanomaterials are already on the market and our regulatory structures aren't necessarily set up to address them proactively. **In fact, the recent Government Accounting Office report posted on the Special Committee website outlines some of these challenges very well. It also describes efforts in several other countries to develop reporting, inventory, and/or disclosure requirements for engineered nanoamaterials:**

http://legis.wisconsin.gov/lc/committees/study/2010/NANO/files/GAO_Nano_report.pdf

The GAO report concludes: *“The use of nanomaterials in products is growing faster than our understanding of the risks these materials pose to human health and the environment. While EPA has taken steps to improve our understanding of these risks, such as by asking companies to voluntarily provide information on the nanomaterials they produce, the information gathered through these efforts has been limited and does not provide a strong foundation for understanding the increasing potential for exposure to these materials as their uses become more prevalent.”* (p. 49).

Reflecting the increasing recognition that U.S. federal level agencies do not have the resources and/or authority (both broadly construed) to keep up with burgeoning nanotechnology developments, the EPA representatives, Jim Alwood and Bradley Grams, who spoke at the Sept. 16 nano committee meeting explicitly encouraged states to develop their own approaches to nanotechnology and said that this would help the EPA's efforts.

5. The letter notes that “the 2011 Budget increase the priority of nano EHS research with a request of \$117 million, more than 27 percent above the 2010 level” and concludes that “the funding for additional research and development of regulations is well underway at the federal level”

These numbers are vague and misleading, as described above. The argument that the federal government is adequately funding nanotechnology environmental health & safety research has been repeatedly refuted in some detail by numerous high-level risk and regulatory policy analysts and reports recently and in the last several years. Again, see numerous reports listed here: <http://www.nanoceo.net/regulatory-issues>

In sum, Dr. Scheufele's claims fail to compare the “request” for EHS funding to “requests” for funding for non-EHS nanotechnology research and development under the NNI—and more importantly, how EHS and non-EHS funding levels have compared since the NNI began. At the Sept. 16th meeting the EPA representatives presented a slide clearly showing that the funding levels for EHS research through the EPA/ORD have consistently been only a small proportion of the total NNI budget (see slide 5 of Jim Alwood's presentation, showing funding levels for the NNI compared to funding levels to the EPA/ORD for nano EHS work). Moreover, funding levels for other agencies that play key roles in protecting environmental and public health and safety are even lower than those provided to the EPA/ORD (see below).

Further, as I and my colleagues at the Wisconsin Department of Natural Resources and UW Law School articulated in a paper published in Environmental Management in 2008, **even if the EPA regulates emerging nanotechnologies/materials, and gathers information similar to the kind**

we would like to see on a state registry—local and state governments charged with monitoring and control by the federal agencies would not have access to much (or any) of this information and therefore it wouldn't provide some of the basic information they need to protect public and environmental health in their jurisdictions. This is one key reason among others why it makes sense to develop effective inventory and disclosure requirements at local and state levels, **not as a replacement for federal regulations, but as a complement to them.** As EPA representatives stated in their testimonies to the Special Nano Committee on Sept. 16 (during the question and answer period), if local and states can gather information about engineered nanomaterials being used and handled in their states, this data will in fact help the EPA and other federal agencies do more comprehensive, appropriate risk assessments and create better policies .

6. Finally, the letter concludes that regulations that are apparently “well underway” at the federal level “will address both workplace and consumer end market EHS issues.”

This is clearly incorrect. Again, I quote the GAO report here: *“EPA has taken some regulatory action with regard to nanomaterials under TSCA and has developed plans to take further action with regard to information collection and testing of nanomaterials. **However, these changes have not yet gone into effect and products may be entering the market without EPA review of available information on their potential risk. Moreover, although EPA requires chemical companies to periodically provide certain information on many of the chemicals currently in commerce, EPA has not extended this requirement to nanomaterials...**”* (p. 49).

While the EPA is beginning to take some concrete regulatory actions (e.g., new significant new use rules, or SNURS, for some carbon nanotubes), these actions are a far cry from saying that regulations are “well underway” and steps that are being initiated now will take a long time to implement fully. Critical information generated from these SNURS, moreover, will not be available to local and state agencies so they can know what's going on in their jurisdictions. Further, there are countless more engineered nanomaterials that many would argue should be addressed through TSCA about are not currently. Developing reporting requirements for some types of carbon nanotubes through TSCA is an important step, but it is a small drop in a huge bucket.

Also, these quotes from the GAO report only refer to the EPA, which has substantially more resources from the NNI and other sources to address nanotechnology EHS issues than other agencies that play equally critical roles in addressing workplace and consumer product EHS issues, such as the Food and Drug Administration (FDA), the Occupational Safety & Health Administration (OSHA), and the Consumer Product Safety Commission (CPSC). These agencies are even further behind, are substantially under-funded, and some of these agencies are doing almost nothing to address nanotechnology EHS issues and have no plans to do so any time soon (other than perhaps writing some reports).

Most problematically, it is hard to see how, even with the best intentions, federal agencies can keep up with and adequately address both workplace and consumer end market EHS issues when their funding to do so is a tiny percentage of the funding going into nanotechnology research and development—through government, industrial, and many other funding sources.

Under these circumstances, developing basic disclosure and reporting requirements at the local and/or state levels now is all the more critical. Doing this could help leverage existing local and state agency resources to at least begin to take steps to prevent human exposures and environmental emissions now especially for nanomaterials that scientific studies are suggesting may cause human and environmental harm (e.g., carbon nanotubes, nanosilver, and several others).

In conclusion, I sincerely hope the committee will take the time to be accurately informed on nanotechnology environmental health & safety policy developments to date, and not be misled by inaccurate claims when they develop nanotechnology policies for Wisconsin. Wisconsin has the chance to be a national leader and an innovator on environmental health and safety policy for nanotechnologies and other emerging technologies--and this means leaving behind inaccurate and out-dated arguments about how basic reporting requirements and other regulations will hurt industry or drive them out of the state. We should not put our heads in the sand as we have in the past and move on to more enlightened, creative, and proactive approaches that serve to protect the workers, citizens, the environment and future generations of Wisconsin.

Thanks for considering my comments.

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