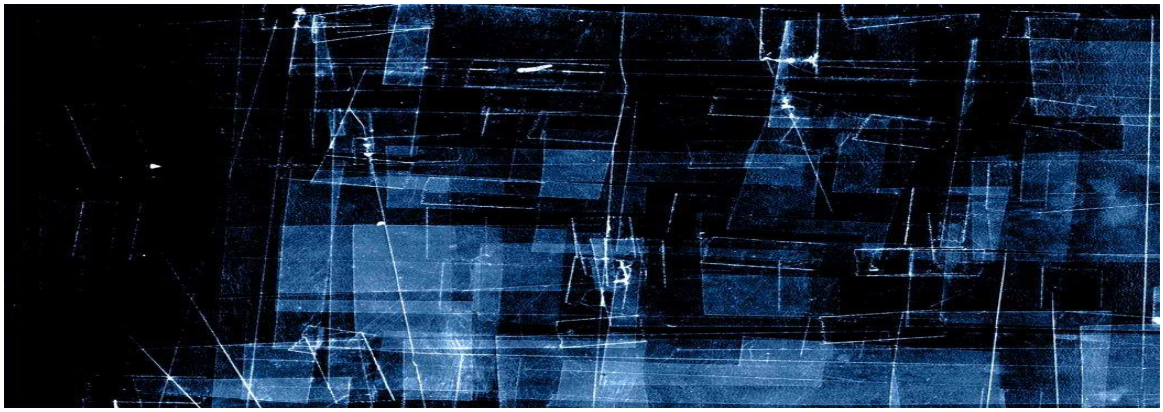

Demands for Regulation of Nano-Silver – The First Battle for the Industry's Future?

Reed D. Rubinstein*

Abstract

An initial shot over the bow has been fired at the nanotechnology industry by a non-profit organization whose avowed purpose is to "[h]alt the commercialization of nanotechnology until products containing nanoparticles have been proven safe." The International Center for Technology Assessment (ICTA), along with other special interest groups, filed a 116-page petition with the U.S. Environmental Protection Agency, demanding that EPA regulates all nano-silver products as pesticides, and stops the use or sale of all consumer products containing nano-silver, under FIFRA, the Federal Insecticide, Fungicide and Rodenticide Act.

Yet, nano-silver is the most prevalent nanomaterial in consumer products today, and is subject to more regulatory oversight and enjoys the most extensive support by available safety and efficacy data of any nanomaterial. This article suggests that the ICTA's petition may be driven more by political agenda than science, and aimed at souring the public's perception of nanotechnology. The author warns the nanotechnology industry not to shrink from engaging in what will be a war worth fighting, but to learn from the mistakes of other industries. Nanotechnology stakeholders should expose the biases, agendas, and dubious funding sources of its critics on the one hand, while proactively preserving consumer faith and confidence, protecting its workers and safeguarding the environment at the same time.

1. Introduction

On May 1, 2008, the U.S. Environmental Protection Agency (EPA) received a 116-page "petition" from a shadowy non-profit organization called the "International Center for Technology Assessment" (ICTA).[1] The Petition demanded, among other things, that the EPA regulate *all* nano-

*Reed D. Rubinstein is shareholder in the Washington, D.C. office of Greenberg Traurig LLP.

silver products as pesticides.[2] The Petition claimed that "research has mounted to indicate that nano-silver materials pose serious risks to human health and the environment,"[3] and it demanded that EPA take action to stop consumer use of all products containing nano-silver.[4]

In response, EPA published notice of the ICTA's petition in the Federal Register for public comment.[5] Well over 1,000 comments were submitted to EPA by the time the comment period closed on March 20, 2009. EPA is reviewing those comments and formulating its response to the ICTA Petition.

2. Analysis

Silver nanoparticles are used in more consumer products than any other nano-material, because silver is a highly effective and safe anti-microbial.[6] The data uniformly suggest that it is non-toxic and non-carcinogenic in humans.[7] Episodes of environmental toxicity resulting from silver pollution are "rare."[8] In fact, at worst, the data suggest only "evidence of potential ecological significance."[9] Harm, if any, appears to be limited to fish and aquatic non-vertebrates.

Enhanced waste-water treatment and the functional termination of silver-based photo developing have combined to significantly reduce environmental discharges of silver wastes. It is possible that the expanding use of nano-silver in consumer products could, in theory, cause silver discharges to increase. However, calculating the amount of such potential nano-silver discharges, much less estimating the environmental impact of such discharges due to the "complex geochemical reactions" in the environment, and the varying toxicity processes within and between species, renders claims of risk highly speculative and empirically unsupportable.[10]

Furthermore, the regulatory environment for nano-silver products is relatively clear and precise. Products that contain nano-silver and make anti-microbial claims must be registered as "pesticides" under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").[11] The

---

[1] The funding and organizational relationship between ICTA and a "sister organization" called "The Center for Food Safety" (CFS) is not entirely clear. However, it appears these organizations have received funds in the past from both the John Merck Fund and the Tides Center/Tides Foundation, among others. It is not clear who funded the EPA Petition.

[2] ICTA Citizen Petition for Rulemaking to the United States Environmental Protection Agency, at 34, 39-42, 115-16 (May 1, 2008), *available at* http://www.icta.org/nanoaction/doc/CTA_nano-silver%20petition__final_5_1_08.pdf.

[3] *Id.* at 16.

[4] *Id.* at 4, 29, 97-99, 115.

[5] *See* 73 Fed. Reg. 69644 (Nov. 19, 2008) (providing notice of availability for review and public comment); *See also* 74 Fed. Reg. 2072 (Jan. 14, 2009) (announcing extension of comment period).

[6] Silver nanoparticles have been incorporated into medical devices, water filters, socks, bedding materials, women's underwear, and even the Hong Kong subway. Samuel N. Luoma, *Silver Nanotechnologies and the Environment: Old Problems or New Challenges?*, Sept. 2008, at 12, PEN 15, *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Nanotechnologies/Nano_PEN_15_Final.pdf.

[7] *Id.* at 26 ("silver is not especially toxic to humans or other mammals").

[8] *Id.* at 14.

[9] *Id.*

[10] *See id.* at 15.

[11] 7 U.S.C. § 136.

registration process involves rigorous and well-understood data, efficacy, and safety requirements.[12] Additionally, EPA has garnered extensive data regarding silver, and has taken significant steps to clarify regulatory uncertainty with respect to the FIFRA registration of silver ion-generating equipment, among other things.[13]

Therefore, on its face, the ICTA petition attacking nano-silver makes little sense. Of all the nanomaterials in use today, none are as subject to as much regulatory oversight, or have as much safety and efficacy data, as silver. And yet, the ICTA has bizarrely demanded that the EPA declare any product containing nano-silver subject to regulation as a pesticide[14] and bar all sales until "proven safe."[15]

The rationale for the ICTA petition, however, becomes crystal clear if politics, power, and political control—and not science—are recognized as the primary drivers of the action.

The ICTA IRS Form 990 tax return states that the organization's purposes include, "Halt the commercialization of nanotechnology until products containing nanoparticles have been proven safe."[16] This assertion, that the commercialization of nanotechnology must be banned until it is proven safe is repeated on the ICTA website.[17] However, the ICTA never defines what it means by "safe" with respect to nanotechnology.[18]

The ICTA seems to suggest that "proving safety" is tested against its variation of the "precautionary principle." Under the ICTA's unique version of this doctrine, which in its pure form aims to balance benefits, risk, and uncertainty, "when an activity raises threats of harm, precautionary measures should be taken even if some cause and effect relationships are not fully

---

12 *See* 40 C.F.R. §§ 152, 158, and 161 (2009).

13 *See, e.g.,* "R.E.D. (Reregistration Eligibility Decisions) Facts, Silver," EPA-738-F-93-005, (EPA Office of Prevention, Pesticides, and Toxic Substances, June 1993) EPA-738-F-93-005, *available at* http://epa.gov/oppsrrd1/REDs/factsheets/4082fact.pdf; *see also, e.g.,* Pesticide Registration: Clarification for Ion-Generating Equipment, 72 Fed. Reg. 54039-40 (Sept. 21, 2007).

14 ICTA Petition, *supra* note 2, at 42.

15 Petition, at 4, 29, 97-99, 115.

16 The other corporate purposes include "encourage restriction and/or regulation of the genetic manipulation of humans," and "educate the public and (sic) effects of global warming," ICTA Form 990 (2007), *available at http://tfcny.fdncenter.org/990_pdf_archive/521/521909699/521909699_200712_990.pdf* (last visited Sept. 2009).

17 The website states:

CTA seeks to halt the commercialization of nanotechnology until products containing nanoparticles have been proven safe. CTA also seeks to force federal regulatory agencies to adopt an accurate and standardized definition of nanotechnology and to regulate emerging nanotechnologies as they would other materials whose safety has not been determined.

Nanotechnology, Tiny Technology, Significant Risk, *http://www.icta.org/nanotech/index.cfm* (last visited Aug. 31, 2009).

18 It is, however, very open about its fears. For example, it states:

Currently scientists find the prospects of containing an oil spill or removing nuclear contamination daunting, if not impossible, tasks. They have been unable to prevent genetic pollution from biotech plants from cross-pollinating with weeds or contaminating other crops. Just imagine the difficulties we would face confronting a microscopic army of self-replicating nanotech robots designed to invade and alter the human body!

Id. (The ICTA does not cite any study or other empirical evidence to support its claims of risk).

established scientifically."[19] ICTA fails to define what "raise a threat of harm" actually means. This is a significant omission, given that the definition presumes that "cause and effect relationships" are not "fully established scientifically." Any potential harm, no matter how remote or speculative, apparently requires some unbounded "precautionary" action. The ICTA's corruption of the precautionary concept renders the doctrine utterly useless as a scientific policy tool, but highly effective as a political one. Friends of the Earth, an organization closely tied to ICTA, drops the veil to reveal that the constant invocations of the "precautionary principle" really mean "nanotechnology's broader socio-economic and political implications [must be] considered and assessed alongside its toxicity risks.[20] This approach, of course, is very different from the principle enshrined (for example) in Article 15 of the Rio Declaration on Environment and Development, which states, "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[21]

The ICTA petition was filed in May of 2008. In February of that year, ICTA published its "Principles for the Oversight of Nanotechnologies and Nanomaterials."[22] Allegedly funded by "the Barbara Smith Foundation,"[23] the document was short on science and regulatory analysis. It was, however, full of exhortatory and meaningless radical political language.

To begin with, the ICTA demanded, "democratic involvement for the entire range of processes by which nanotechnologies are developed and used and is necessary at each stage of development on a continuing basis to ensure that public concerns, values and preferences inform and guide nanotechnology oversight."[24] Rejecting the "false presumption that technological change is inevitable and/or always beneficial," it asserted that "the processes of designing nanotechnology devices and systems should be driven by social needs that are identified through informed deliberation and open decision-making among the affected people."[25] It demanded "[s]pecial efforts" to "include persons living in poor communities, who have suffered disproportionately from the development of new technologies in the past."[26]

In addition to admittedly unknown "health, safety and environmental risks," the ICTA claimed that nanomaterials "present broader socio-economic concerns. For example, as new nanomaterials gain widespread use, they may disrupt markets for existing commodities, with potentially devastating consequences for the economies of commodity-dependent developing countries (i.e., the poorest countries)."[27] Apparently in opposition to basic intellectual property norms, the ICTA decried "granting patents for fundamental nanomaterials, which may amount to privatizing the

---

[19] ICTA, et al., Principles for the Oversight of Nanotechnologies and Nanomaterials 4 (Feb. 18, 2008), *available at http://www.nanoaction.org/nanoaction/doc/nano-02-18-08.pdf*.

[20] Friends of the Earth Nanotechnology Project, *Who's Afraid of the Precautionary Principle? http://nano.foe.org.au/node/186* (last visited Aug. 31, 2009).

[21] United Nations Environment Programme, http://www.unep.org/Documents/Default.asp?DocumentID=78&ArticleID=1163.

[22] ICTA, "Principles," *supra* note 19.

[23] Data regarding this foundation, including its IRS Form 990 tax filings, were not readily available.

[24] "Principles," *supra* note 19, at 9.

[25] *Id.*

[26] *Id.*

[27] *Id.* at 10.

building blocks of the natural world ...."[28] Finally, it asserted that "Social impact, ethical assessment, equity, justice and individual community preferences should guide the allocation of public funding for research. A significant proportion of this research should be community-based and designed to encourage public participation."[29] The ICTA did not define "equity," "justice," "community-based research," nor whom, in its view, was qualified to articulate "individual community preferences."[30]

It is clear that the business of striking a balance between benefits and empirically verifiable risks is essentially irrelevant to the ICTA and other like-minded organizations. In truth, the ICTA's Petition is nothing but a proxy battle, a first step in a long-term strategy to cripple innovation, stop technological advancement, and derail private sector economic growth in favor of a program based on collectivist, statist command and control. Sound science is entirely beside the point—a desire for political control over the economy and technology is the crux of the matter.

If the EPA responds to the ICTA petition based on the science and the law, rather than based on politics, then it shall emphatically reject its claims, its conclusions, and its demands. However, the ICTA petition illustrates in graphic detail the political challenges faced by the nanotechnology industry. The industry's most significant threat is not necessarily science or safety—it is instead the propaganda of ideologically committed opponents. The ICTA and others like it are waging a propaganda war to win the hearts and minds of consumers, and this is a war that the industry must win.

A recent study conducted by the Cultural Cognition Project at Yale Law School in collaboration with the Project on Emerging Nanotechnologies suggests that the highly politicized nature of the opposition to nanotechnology needs to be exposed. The Yale study involved a diverse sample of 1,800 Americans, the vast majority of whom were unfamiliar with nanotechnology. When shown balanced information about the risks and benefits of nanotechnology, study participants split on its safety. Cultural values determined how people responded.[31] People with traditional values read the data to mean that nanotechnology is safe and beneficial. Those who favored collectivism read the same data to mean that nanotechnology is likely to be dangerous.[32]

Author Jonathan Rauch began a 2003 article for the *Atlantic Monthly* titled "Will Frankenfood Save the Planet?" with the premise that "genetic engineering" for agricultural purposes "may be the

---

[28] *Id.*

[29] *Id*.

[30] *See generally id.* at 9–11.

[31] Press Release, Yale Law School, *YLS's Cultural Cognition Project Finds Emotions and Values Shape Public Perception of Nanotechnology*, (March 7, 2007), *at* http://www.law.yale.edu/news/4774.htm. The study states: "Members of the public are likely to polarize on the safety of nanotechnology along exactly the same lines that now characterize disputes over nuclear power, global warming and other contentious environmental issues absent a major public education effort by industry, government, civic groups and scientists."

[32] The study's results were consistent with prior studies examining how people's cultural values influence their perceptions of environmental and technological risks generally. According to Prof. David Kahan, the study's lead author:

> We found that when people who hold largely "individualistic" values—and who tend to dismiss claims that commerce and industry are dangerous and need regulation—receive information about nanotechnology, they tend to focus on the benefits. When those who hold "egalitarian" and "communitarian" values—and who are relatively more community-oriented and sensitive to environmental and technological risks—get the same information, they focus on the risks.

most environmentally beneficial technology to have emerged in decades ….if the planet is fortunate, [this is] the farming of the future."[33] Environmental groups had savaged agricultural bio-genetics during the 1990s, and convinced consumers that genetically engineered plants posed an existential risk to the environment and human health. But Rauch, after a hard look at the science and the realities of population growth and crop yields, came to a different conclusion. He wrote:

Other groups argue for what they call the Precautionary Principle, under which no transgenic crop could be used until proven benign in virtually all respects ….Under this policy, the cleaner water and healthier soil that [farming with genetically engineered plants] has already brought to the Chesapeake Bay watershed would be undone ....For reasons having more to do with politics than with logic, the modern environmental movement was to a large extent founded on suspicion of markets ….[However] In ten years or less, most American environmentalists (European ones are more dogmatic) will regard genetic modification as one of their most powerful tools ….the environmental logic of biotechnology is ….compelling.[34]

The biotechnology industry, focused on developing better plants to produce more food, protect the environment, and alleviate world hunger, was entirely caught off guard by activist attacks. The industry's response was tepid and ineffectual. And human suffering was the result.[35]

3. Conclusion

The ICTA Petition is but the first step in what will likely be a long and bitter war. Therefore, the nanotechnology industry must learn and not repeat the mistakes made by others. It must take effective steps to preserve consumer faith and confidence. It must protect its workers, and take reasonable steps to safeguard the environment.

At the same time, it must aggressively respond to its critics, to highlight their biases and agenda. It must expose funding sources, and demand transparency of funding, purpose, and intent. The promise and environmental logic of nanotechnology is worth defending and too compelling to be lost. And yet, lost it will be, unless the industry is prepared to stand up and fight back.

---

[33] Jonathan Rauch, *Will Frankenfood Save the Planet*?, THE ATLANTIC MONTHLY, Oct. 2003, *available at http://www.theatlantic.com/doc/200310/rauch*.

[34] *Id.*

[35] During the severe African famines of 2002, Zambia, among others, rejected food aid based on entirely unfounded fears of bioengineered crops, fears fed by irresponsible Western critics. According to one contemporaneous report:

> As the country reels in hunger and starvation occasioned by crop failure and severe drought, the government has rejected relief food from the West in the form of genetically modified maize. Zambia, like several other countries in the Central and Southern African region, has been hit by a serious food shortage, a situation that has led the government to declare most parts disaster areas. Over two million people have been affected by hunger as a result of grain shortages following a devastating drought that has rocked the country. Zambia alone, needs not less than 200,000 tonnes of maize grain to feed those affected both in rural and urban areas . . . . Zambian President Levy Mwanawasa categorically stated in an interview with British-based Sky News, "We would rather starve than get genetically modified foods without establishing its safety."

See Gershom Ndhlovu, *Zambia Rejects Genetically Modified Food Aid*, (Aug. 19, 2002), http://www.newsfromafrica.org/newsfromafrica/articles/art_851.html.