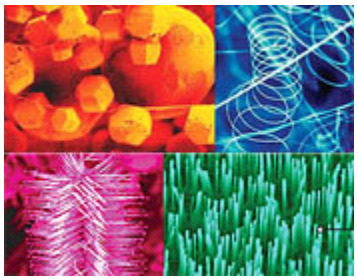
NANOTECHNOLOGY

Untold Promise, Unknown Risk

Consumers Union, July, 2007



Imagine these technological marvels: drugs that seek out and destroy cancer cells, paint that changes color when viewed from different angles, molecular “ink” that encodes millions of pages of information in a square inch, and contact lenses that let you check your blood sugar by just looking in the mirror.

Those and a host of other innovations are already here, or soon will be, thanks to a scientific revolution called nanotechnology, which promises to change our world as profoundly as did electricity and the internal combustion engine.

Nanotech researchers create new materials in two main ways. They can reduce the particles in standard materials to sizes as small as a nanometer, or about one-hundred-thousandth the width of a human hair. At the nanoscale, where the mind-bending principles of quantum physics can apply, the characteristics of materials change: Carbon becomes 100 times stronger than steel, aluminum turns highly explosive, and gold melts at room temperature.

In addition, researchers can manipulate individual atoms and molecules, like tiny Lego pieces, to form microscopic tubes, spheres, wires, and films for specific tasks, such as generating electricity or transporting drugs in the body.

Exploiting the vast potential of those discoveries, manufacturers are bringing nanoengineered products to market at breakneck speed, spurred by a torrent of federal funding since 2001 for research and development. About $2.6 trillion worth of goods worldwide are expected to use nanotech by 2014, up from $50 billion in 2006. “Nanotechnology is creating fundamental changes in almost everything on earth,” says Mike Roco, the National Science Foundation’s senior adviser on nanotechnology, “and what we’re seeing now is just a hint of what’s to come."

But a growing number of scientists say the unique properties of nanomaterials might pose substantial risks, which are largely unexplored, to both human health and the environment. “The more we know about nanomaterials’ risks, the more we worry about what we don’t know,” says physicist Andrew Maynard, science adviser for the Project on Emerging Nanotechnologies at the Woodrow Wilson Center, a nonpartisan public-policy institute in Washington, D.C.

Nanotechnology: Cause for concern

No confirmed cases of harm to humans from manufactured nanoparticles have been reported, though government and industry monitoring has been minimal. But there is cause for concern about the adequacy of regulation as well as several worrisome findings from the limited laboratory and animal research so far:

- Benign materials can become toxic when nanosized because microscopic particles tend to react more readily with human tissues and other substances. One test-tube study, for example, suggested that nanoparticles might help transform proteins into substances linked with Alzheimer's, Parkinson's, and other diseases, though the clinical significance, if any, of that finding is not known.

- Nanoparticles can enter the body and its vital organs, including the brain, much more easily than can larger particles. And they're now used in food additives, cosmetics, and other products that are ingested or applied to the skin. It's likely that "humankind has never been exposed to such a wide variety of substances that can penetrate the human body apparently unhindered," concluded a report on nanotechnology from insurance-industry giant Swiss Re, whose fortunes depend on adequate risk assessment. It recommended protective steps, even if the risks haven't been proved.

- Some nanomaterials seem to linger in the environment--especially in the water supply, where studies suggest they can damage the ecosystem.

- Traditional safety-assessment methods are not adequate for nanomaterials, which might pose very different risks from those of the same materials at conventional size. Yet of the more than $1 billion the U.S. government spent last year on nanotech research, estimates indicate that only 1 percent to 4 percent went to risk assessment.

Consumers have been left in the dark. More than 80 percent of Americans have heard little or nothing about nanotechnology, according to a March 2007 study led by Yale University researchers. One likely reason: Manufacturers aren't required to disclose nanotechnology information or the presence of nanomaterials in their labeling.

Fearing that concerns about possible risks will trigger a consumer backlash, some manufacturers avoid the term "nano." At a congressional hearing last year, Matthew Nordan, president of Lux Research, a market-research firm specializing in nanotech, repeated what he said one corporate executive told him: "You won't hear us talking about nanotech or advertising it in any way. That's our strategy for dealing with potential negative publicity."

As a first step toward filling the nanotechnology information gap, this report launches our coverage of nanotechnology. In addition, the nanoparticles in suncreens and our sunscreens Ratings (available to subscribers) include our first test to detect nanoingredients in consumer products.

Nanotechnology: Great potential

Nanoparticles already exist in nature, as volcanic ash and tiny salt crystals in ocean breezes, for example. And people have long created hazardous nanopollutants, for instance in welding fumes and diesel exhaust. But now scientists using powerful microscopes and other tools can artificially create a vast array of nanoparticles that never existed before, permitting development of innumerable new products. While some of them might be more hype than substance, such products are appearing in almost every arena, particularly the following:

Health and medicine. Nanodelivery systems that precisely target tumors might improve the treatment of cancer. For example, CytImmune, a company based in Rockville, Md., is testing a treatment that uses gold nanoparticles as Trojan horses to deposit toxic anticancer drugs directly into tumor cells. “Nanomedicine promises to make cancer a manageable, chronic disease rather than a life-threatening one,” asserts CytImmune’s president, Lawrence Tamarkin.

Nanotech offers other promising medical applications. A filter with nanosized pores, for example, could permit creation of a wearable or implantable artificial kidney. Researchers are even developing nanogenerators that might one day convert energy from the motion of blood flow into electricity to power a pacemaker.

Energy and environment. Nanotech solutions might lead to clean energy sources and help protect the environment. “Intelligent” nanocoatings for windows that reflect solar heat in the summer and transmit it in winter are already available. So are nanotech methods of removing pollutants from water supplies. Nanosolar, a company based in Palo Alto, Calif., is building what might be the world’s largest solar-cell factory to produce cells at one-tenth the current cost, using nanoparticles of a new semiconductor material printed on thin metal sheets, much like ink on paper. On the drawing board are techniques for desalinating seawater and for conserving energy via cost-effective light-emitting ceilings and walls.

Consumer products. Numerous items produced using nanotechnology might already be part of your daily life. About 60 percent of cars, for example, now have fuel lines made with carbon nanotubes, which might reduce the risk of explosions by inhibiting static electricity. And Eagle One’s NanoWax supposedly fills scratches and gives a glossier shine. It scored well in our July 2006 tests (available to subscribers), but we didn’t test for the presence of nanoparticles, and two apparently conventional waxes scored higher.

In addition, Home Depot sells Behr paint, which supposedly contains nano-ingredients that resist mildew and grease stains. Nanotechnology has even led to fabrics that are claimed to resist odors or stains. In May 2003 we tested the effectiveness of two stain-resistant slacks (available to subscribers), Eddie Bauer’s Nano-Care Chinos (the current version is Nano-Tex Chinos) and Lee Performance Khakis, although we did not verify their nano claim. We found that the pants repelled water-based liquids but not

other stains.

The next stage of nanotechnology has already begun, with scientists “growing” nanomaterials. Researchers at the Massachusetts Institute of Technology, for example, have turned benign viruses into nanofactories that assemble battery parts capable of storing three times as much energy as traditional materials. First they genetically engineer viruses that coat themselves with electrically conductive metal ions. The viruses then align themselves into a bundle that serves as a battery electrode. Prototypes of the tiny batteries should be available within two years. The researchers’ next goal: self-correcting nanomaterials that could repair themselves if, for example, you crack your BlackBerry.

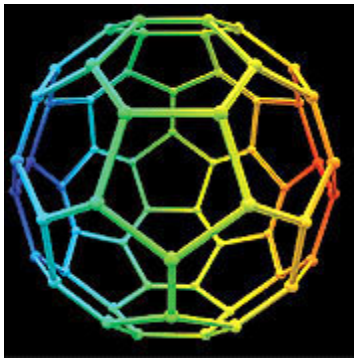
Possible risks: No small matter

The same qualities that make nanomaterials so promising also create the potential to do harm in unexpected ways. The smaller the particle, for example, the more atoms there are on its surface rather than hidden inside. The more surface atoms, the more likely the particle is to react chemically with other compounds. As a result, elements that are harmful in conventional form can become more dangerous as nanoparticles, and even normally benign substances might become toxic when nanosized.

The limited nanotechnology information and research so far indicates that some nanoparticles can bypass the body’s defenses. For example, they can reach the brain by entering the nasal passages and traveling along the odor-detecting nerve. They can move from the lungs into the blood and then to other organs. Ingested nanoparticles seem to reach the organs more readily than larger particles. And at least some of them can pass through the skin.

“Nanoparticles aren’t necessarily hazardous, and most may turn out to be harmless,” but we need to identify “the bad actors,” says Gunter Oberdorster, a nanotech researcher at the University of Rochester. Here’s what’s known about the risks of the most commonly used nanomaterials in consumer products:

Fullerenes. Recent studies have shown that fullerenes, composed of spherically arranged carbon atoms, might damage cells in fish, kill other aquatic microorganisms, and harm human liver cells and DNA. Moreover, they can penetrate the skin, at least when it’s repeatedly stretched.



FULLERENES These carbon spheres are hollow and exceptionally strong

But manufacturers are already using fullerenes in cosmetics, fuel cells, and many other products. Since fullerenes can act as antioxidants, companies using nanotechnology such as Sircuit Cosmeceuticals in Los Angeles and Zelens in London, have developed “anti-aging” facial creams containing them. Zelens boasted on its Web site in late April that the C-60

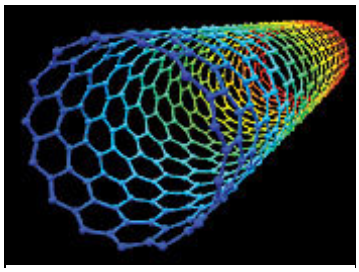
fullerenes (composed of 60 carbon atoms) in its $300-per-ounce night cream are “Nobel Prize-winning ingredients."

We asked Harold Kroto and Robert Curl, who shared with the late Richard Smalley the 1996 Nobel prize in chemistry for constructing C-60 fullerenes, whether their discovery should be used in cosmetics. “I wouldn’t put C-60 on my skin,” Kroto said. Curl agreed, saying he would not expose himself “to a new substance for essentially trivial reasons."

Asked about those comments, Zelens’ commercial director, Elliott Goldstein, said that the company has done “a wide range of tests” on the C-60 creams and “has no concerns” about their safety. Nevertheless, he said the company is replacing them with versions that don’t contain fullerenes. Sircuit’s president, Michael Wolfgeher, said research has shown that the fullerenes in his company’s cosmetics, which cost $110 to $150 per ounce, are “safe and extremely beneficial."

The Food and Drug Administration generally does not review the safety of cosmetic ingredients before they’re sold. And the industry’s Cosmetic Ingredient Review board has not evaluated whether nanoingredients are safe. But industry spokesman John Bailey says fullerenes have been added to the list of ingredients that manufacturers are supposed to identify in cosmetic labeling.

Carbon nanotubes. These tube-shaped structures are typically sealed in composites for auto-body parts, electronic equipment, and sports gear. So they’re unlikely to become airborne during normal use, though that might happen when nanotechnology products are thrown away or incinerated. Currently, lab and factory workers probably face the most exposure.



NANOTUBES These carbon tubes are extremely strong and conductive

Nanotubes and asbestos have similar fibrous shapes. Preliminary findings from the National Institute of Occupational Safety and Health (NIOSH) have suggested that one type of nanotube, called multiwalled, did not act like asbestos in the body.

But several animal studies of single-walled nanotubes, the other common type, indicate that they can inflame the lungs. One study found rapid lung damage in mice exposed to the equivalent of the workplace limit for another form of carbon. An accompanying commentary on that study warned that nanotube workers might therefore be at risk for pulmonary fibrosis, or potentially fatal scarring of the lungs.

Silver. Nanoparticles of silver generate silver ions, which inhibit bacterial growth. Nanosilver products promoted for their antibacterial power include refrigerators with silver-coated interiors, bandages, and toothbrushes. Whether silver nanoparticles or ions pose health risks is not known. But the National Association of Clean Water Agencies is concerned about their environmental impact. Noting that “silver is highly toxic to aquatic life,” the group asked the Environmental Protection Agency in early

2006 to regulate as pesticides all products that release silver particles.

That action was prompted by the sale of products produced using nanotechnology such as Samsung's SilverCare washing machine, which deposits silver ions into clothing during the wash cycle. When we tested that product last year, it inhibited the subsequent development of odors in washed clothes more effectively than other machines but was no better at removing dirt and stains.

Late last year the EPA informed Samsung that its washer would indeed be regulated as a pesticide. Samsung spokeswoman Deborah Szajngarten says the company will continue to sell the appliance and will make sure it meets government regulations, though she adds that the company's tests indicate it is safe.

When the EPA announced the Samsung decision in November 2006, agency spokeswoman Enesta Jones said that silver-containing products would not be regulated if their maker didn't make a pesticide claim. Around that time, certain antibacterial claims and references to silver nanoparticles disappeared from online descriptions of products such as Sharper Image's FresherLonger Miracle Food Storage containers. The company did not answer our e-mailed request for comments.

The EPA said in December that it would publish a formal policy on silver-releasing products. That policy had not appeared at the time of this report.

Nanotechnology: Protecting workers

Some nanotech companies have developed programs to protect workers by monitoring nanoparticle exposure and watching for signs of nano-related health problems. But the majority do not appear to take such proactive approaches.

Late last year the International Council on Nanotechnology (a consortium of experts from the public and private sectors, including Consumers Union, the nonprofit publisher of *Consumer Reports*) released a survey of 64 nanomaterial manufacturers and labs. It showed that only about one in three monitored exposure to the substances. About 38 percent believed their nanomaterials posed no special risks, and another 22 percent didn't know whether they did; the remaining 40 percent said they had safety concerns.

When our reporter toured a plant in Atlanta operated by nGimat, a producer of nanopowders for food packaging, catalysts, and other products, company founder Andrew Hunt said he doesn't do workplace monitoring and doesn't consider nanopowders toxic. "Very few nanomaterials have evidence of toxicity other than if the element itself is toxic," he said.

Not so, says Ken Donaldson, professor of respiratory toxicology at the University of Edinburgh and a leading authority on particle toxicology. Donaldson says scientific evidence shows that "smallness in and of itself" can transform normally benign

substances into harmful ones. For example, titanium dioxide has long been used safely as a paint pigment. But animal studies show that nanoparticles of the compound can damage the lungs.

Even scientists who are developing new materials using nanotechnology don't know enough about the risks, says Maria Powell, a researcher in the Nanoscale Science & Engineering Center at the University of Wisconsin-Madison. "Some of the Ph.D.s think concerns about nanomaterials are being cooked up by a bunch of crazy environmentalists," says Powell, who has interviewed scientists in many labs.

Researchers at Savannah River National Laboratory have found several instances of risky handling of nanoparticles. Workers at one laboratory, for example, did not know that some nanoparticles are extremely combustible. So they were startled when a rag that contained nanoparticle residues spontaneously burst into flames.

Britain's Royal Society and Royal Academy of Engineering have recommended avoiding the release of nanoparticles into the environment and urged factories and nanotechnology labs to treat the particles "as if they were hazardous." But in the U.S., "it's like the Wild West because people working with or transporting these materials often don't even know what they're handling," says Bill Kojola, an industrial hygienist at the AFL-CIO.

Despite the possible risks, anyone with a credit card can buy carbon nano--tubes from -mail-order suppliers such as CheapTubes, in Brattleboro, Vt., whose Web site proclaims, "We search the world for the highest quality lowest cost carbon nanotubes so YOU don't have to!!!"

We ordered single-walled carbon nano-tubes from CheapTubes, which shipped $150 worth of the powder in an antistatic zipper-locked bag inside a second bag sent in a padded envelope via U.S. Postal Service overnight mail. We sent the package to an outside lab, which verified that it contained nanotubes.

CheapTubes's president, Mike Foley, says that the packaging is designed to prevent release of nanotubes, and that he has received no reports of bags being torn during shipping. But when we asked Wilson Center science adviser Maynard about the company's methods, he said "it's hard to imagine circumstances in which shipping such a powder in plastic bags would be considered good practice."

We also asked Maynard to assess the online version of the safety data sheet that CheapTubes encloses with the shipments. He called it inadequate, saying it doesn't reflect current research on nano-tubes' toxicity. Foley says the sheet was the best he could find when the company was started two years ago. At the time of this report, he said he will be amending the data sheet to include more safety information.

Nanotechnology: Protecting consumers

FDA regulation of nano-ingredients is particularly crucial, since the agency oversees products that go directly onto or into the body. But the government's 2007 budget request for nanotechnology research includes nothing for the FDA.

The agency itself must reassess its regulatory policies, says former FDA official Michael Taylor. Its Web site says "existing requirements may be adequate for most nanotechnology products that we will regulate." In contrast, scientific and government panels in Europe call for testing, approving, and regulating nanomaterials as new chemical substances.

In May 2006, the International Center for Technology Assessment in Washington, D. C., and other advocacy groups filed a petition with the FDA demanding new regulations for products with nanoingredients. The petition argued that the agency failed to properly review the safety of nanoscale titanium dioxide and zinc oxide in sunscreens.

Commenting on the petition last year, Cosmetic, Toiletry and Fragrance Association vice president John Bailey said the particles are tested for safety before they're sold and "have been affirmed to be safe by the FDA." But when *Consumer Reports* filed a request under the Freedom of Information Act to obtain copies of the safety documentation the FDA purportedly reviewed, its response did not include any scientific evidence.

FDA spokeswoman Susan Cruzan says a Nanotechnology Task Force formed several months after the petition was filed is evaluating whether nanoscale materials warrant additional safety reviews and whether labeling will be required for personal-care products.

Using nanotechnology: What must be done

Manufacturers using nanotechnology seldom label products to show the presence of nanoingredients. Even when they do, consumers cannot determine whether those ingredients are safe. So Consumers Union believes the responsibility for protecting consumers rests mainly with government and industry. In particular, the U.S. government must do the following:

- Improve FDA oversight. The agency should assess safety information on nanoingredients in cosmetics, food additives and supplements, and drugs before they're sold. It should also require manufacturers to report health problems linked to those ingredients, former FDA official Taylor argues. That's crucial because under the current voluntary system, companies are unlikely to file the equivalent of a "kick me here" sign that could trigger FDA action, says lawyer Sanford Lewis, co-author of a recent report on the safety of cosmetics.

- Make labeling mandatory. That should apply to all items regulated by the FDA.

Labeling informs consumers and enables researchers and regulators to link cases of health or environmental damage to particular nanomaterials. In addition, the Federal Trade Commission should consider charging companies that use nanotechnology with false or misleading advertising if their marketing fails to disclose the presence of nanomaterials or makes inappropriate safety claims

- Provide more funds for risk research and regulation to the FDA, NIOSH, EPA, and the Consumer Product Safety Commission. Last year the Wilson Center urged the government to devote at least $100 million over the next two years to high-priority nanotech-risk research. But it now spends only about one-fifth that amount, the center estimates.

- Consider new safety legislation. The Wilson Center asked J. Clarence Davies, who co-wrote the plan that created the Environmental Protection Agency and wrote the landmark law giving it oversight over chemicals' safety, to analyze whether current laws were sufficient to manage the possible risks of nanotechnology. Initially skeptical about the need for new legislation, Davies changed his mind as he learned more, and recommended a new law that would focus on premarket risk assessment. His report concluded, "Once nanotechnology materials get into the environment, it is probably too late for remedial measures."

Some entrepreneurs share that concern. Seth Coe-Sullivan, chief technology officer at QD Vision, a nanotech start-up in Watertown, Mass., says he and others in the industry are mindful of the potential risks and are trying to develop nano-technology responsibly. "Unless we put the safety of consumers and the environment first," he says, "nanomaterials could end up being asbestos writ small."

Nanotechnology: Our first test

Nanoparticles are found in many sunscreens

Many sunscreens contain nanoparticles of zinc oxide or titanium dioxide, even though you probably won't see the term "nano" on the labels. Whether smearing those nanoparticles on your skin can harm your health is not clear. But you don't generally need them to get superior protection, our tests of 19 sunscreens found.

Nanoparticles of the two compounds are used in sunscreens because the normally white substances, which absorb ultraviolet radiation, become more transparent when the particles are nano-sized. We asked an outside lab to test for those nanoparticles in eight sunscreens that listed either compound on their label. All contained the particles, yet only one, Keys Solar RX, disclosed that use of nanotechnology.

Lab studies indicate that both of those nano-ingredients create free radicals that

damage the DNA of cells and possibly cause other harm as well. And even low exposure to nanoparticles of titanium dioxide can damage the lungs of animals if inhaled.

But whether those particles in sunscreens pose direct health risks to humans depends mainly on whether they penetrate the protective outer layers of dead skin. Studies suggest they don't reach live tissue under normal circumstances. But it's not known whether skin damaged by acne, eczema, sunburn, or nicks from shaving is more vulnerable to penetration, says Kristen Kulinowski, director of the International Council on Nanotechnology, which promotes responsible development of nanotech. And studies of other nanoparticles show they can penetrate the outer skin layers through the hair follicles or when the skin is repeatedly stretched.

Bottom line. Until there's adequate safety assessment, people who wish to avoid exposure to those nanoingredients could choose sunscreens that don't list titanium dioxide or zinc oxide on their label. That wouldn't require settling for less sun protection: Our tests found no correlation between effectiveness and the presence of those ingredients. Moreover, the top-scoring U.S. product, Neutrogena Ultra Sheer Dry-Touch SPF 45, did not contain either zinc oxide or titanium dioxide.

INVISIBLE INGREDIENTS Microphotographs we commissioned found nanoparticles of zinc oxide, titanium dioxide, or both (top), in eight sunscreens. But only Keys Solar RX (bottom) labeled its nanosized ingredient.

Here or coming soon

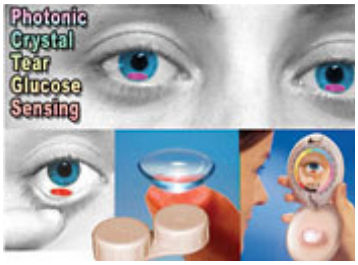
Striking uses of nanotechnology

Automobiles

What This zero-emission, $45,000 Phoenix electric truck is powered by Altair Nanotechnologies' NanoSafe battery, which can be charged in as little as 10 minutes. It travels about 130 miles between charges.

When Available in 2008 or 2009.

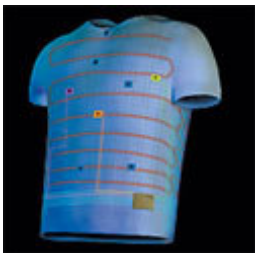
Smart eyewear



What Contacts with a color-shifting sensor are being developed at the University of Pittsburgh. They let people with diabetes check their blood-sugar level just by glancing in a mirror.

When Expected within five years.

Smart clothing



What Sensatex's SmartShirt incorporates an electrically conductive grid of nanofibers to allow remote monitoring of your heart rate and other vital signs.

When Expected within a year, pending current testing.

Electronics

What Inside many new computers, such as Apple's iMac, is an Intel chip containing transistors so small that 100 would fit inside a single human cell. The microscopic circuitry uses less power while boosting performance.

When Available now.

Food safety

What Cornell researchers are developing swabs containing nanosensors that can detect E. coli; avian influenza A (H5N1), the bird-flu virus; and other nasty bugs on countertops or in food, for example.

When Expected within five years.

Appliances

What Nanosilver linings in Samsung's Quatro refrigerators supposedly inhibit growth of mold and odor-causing bacteria.

When Available overseas now, expected soon in the U.S., pending EPA approval.

Sports gear

What Lightweight, high-strength golf clubs as well as balls that supposedly provide truer putts and straighter drives.

When Available now.

Nanotechnology

What you can do

Check for nanoingredients. While most product labels do not reveal the presence of these ingredients, some do. So look at labels, especially on items that you ingest or apply to your skin. (Nanoparticles sealed in coatings or composites probably create little direct exposure.) Labeling at least lets consumers decide whether to buy a product despite unknown risks. And go to *www.nanotechproject.org/44,* part of the Web site of the Wilson Center's Project on Emerging Nanotechnologies, which lists more than 470 products advertised or labeled as containing nanoingredients.

Learn more about nanotechnology. Go to the site of the Wilson Center *(www. nanotechproject.org);* the International Council on Nanotechnology, or ICON *(www. icon.rice.edu);* or Consumers Union *(www.ConsumersUnion.org/products).*

Speak up. Contact government agencies such as the FDA *(www.fda.gov)* and the National Nanotechnology Coordination Office *(www.nano.gov/html/about/nnco.html)* as well as manufacturers, researchers, and public-interest groups at the ICON Web site.