Gen Re Research

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Insurance Issues™

Contents

About this Newsletter

Created for our clients, our *Insurance Issues* publication series provides an in-depth look at timely and important topics on insurance industry issues. To speak further with Gen Re about any nanotechnology questions, please contact your Treaty or Facultative representative.

Nanotechnology—The Smallest and Biggest Emerging Issue Facing Casualty Insurers?

by Charlie Kingdollar, Gen Re, Stamford

The expanding use of nanotechnology may be one of the most important, and possibly the most ignored, emerging issues facing the property/casualty insurance industry. As a refresher, nanotechnology is loosely defined as the ability to organize and manipulate matter at sizes where at least one dimension is 100 billionths of a meter or smaller. (This is only a working definition and may still be amended.)

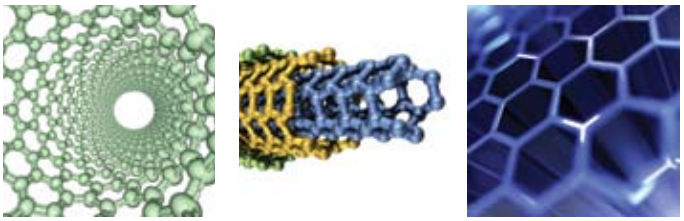
Nano-sized particles exhibit unique properties relative to larger particles of the same substance. Nanotechnology researchers are creating extraordinary *new* substances. Nanotechnology will undoubtedly bring about myriad scientific, material and medical advancements that will provide many benefits to society. It has been considered by some to be the next industrial revolution, with an expectation that it will create much needed job growth. Little, however, is known about the toxicity of nanomaterials or the potential for latent illnesses that could affect workers and consumers. There are, at this time, dozens of studies associating exposure to various nanomaterials with adverse health effects. The vast majority of these are studies on small animals. There is currently little in the way of federal or state regulation regarding the manufacture or use of nanomaterials and no labeling requirements for consumer products.

Perhaps most importantly for insurers, exposure to nanotechnology is not a distant concern that awaits us sometime in the future. Thousands of tons of various nanomaterials are currently being manufactured annually and are being incorporated into thousands of products. The list of products containing nanomaterials has become far too long to detail here, but includes: cosmetics, personal care products, computer chips, electronics, paints and coatings, cleansers, lubricants, textiles, building materials, sports equipment, automobile and aircraft parts, food containers and plastic wrap, animal feed, medicines and food products and additives.

It is also important to note that in the U.S. there are at least 1,000 nanotechnology firms that each employ fewer than 25 people. Many of these firms may currently buy insurance coverage on standard occurrence-based policy forms. Some may even write coverage on BOP or CPP policy forms with little to no underwriting of the potential nanomaterial exposures and for a premium charge that does not reflect the potential high hazard exposure of these risks.

Even insurers who avoid manufacturing risks or product liability may unknowingly have exposure to nanotechnology risks from products that are manufactured in other countries. Should the nanomaterials in these products result in illnesses, U.S. distributors and retailers could incur liability.

In our effort to stay on top of nanotechnology exposures, Gen Re attended the 5th International Symposium on Nanotechnology, Occupational and Environmental Health held in Boston in August 2011. The event had some 350 attendees—which overwhelmingly included research PhDs, toxicologists, industrial hygienists, nanotechnologists (the first time we've heard this title used), and a few vendors. According to the list of attendees, only four people from the insurance industry attended, including this author. Dozens of speakers from as many countries gave presentations on nanotechnology research and the state of the industry during the conference. This publication outlines some of the highlights garnered from the presentations.



State of the Nanotechnology Industry

What's in a name? Possibly due to studies that found the potential for adverse health effects arising from exposure to various nanomaterials, some companies have moved away from the term "nanotechnology," "nanomaterial" or "nanoparticle." Instead, they have begun to use the term "ultrafine particles" to describe substances of under 100 nanometers in size. Another term we heard for the first time at this conference was "advanced nanomaterials." These were described as including self-powered and self-propelled nanomaterials.

According to the federal government's National Nanotechnology Initiative, over the past 10 years the U.S. nanotechnology industry has grown 16% to 33% annually. The U.S. government has spent over $16 billion on nanotechnology development since 2000 (including approved 2012 budget year funding). The overwhelming majority of expenditures have gone to development of nanomaterials. Little has been directed to health, safety or environmental concerns. In 2010 approximately $110 billion of consumer products containing nanomaterials were sold, down from 2009's $159 billion in sales and possibly related to the recession.

As of 2009, it was estimated that there were some 180,000 workers employed by the U.S. nanotechnology industry. Given 16% to 33% annual growth in the U.S. nanotechnology industry, this could mean that there are currently between 240,000 and 320,000 U.S. nanotechnology workers—not including employees working with nanomaterials in secondary industries.

According to spokespeople for the federal government's National Institute for Occupational Safety and Health (NIOSH), companies engaged in nanotechnology have, on average, 75 nanomaterial workers. Presumably this includes all companies working with nanotechnology, including Fortune 500-type firms. NIOSH expects there will be some 800,000 nanotechnology workers employed in the U.S. by 2015. The number of nanotechnology companies worldwide is now estimated to include some 5,400 firms.

Occupational Exposure to Nanomaterials

Currently, researchers addressing occupational exposure to nanomaterials are generating more questions than answers. NIOSH speakers spent a considerable amount of their presentation time discussing occupational exposure to carbon nanotubes (CNTs). One NIOSH representative stated that an occupational exposure level of between 0.2 micrograms (mg) of CNTs per cubic meter of air and 2 mg of CNTs per cubic meter of air over an eight-hour period resulted in weighted average indications of a more than 10% increase in the risk of early stage adverse lung effects.

NIOSH had previously published a recommended exposure limit (REL) of 7 mgs of CNTs per cubic meter of air, but given recent studies and advancements in the ability to measure nanomaterials in the air, the agency is planning to lower the REL to 1 mg per cubic meter of air. One NIOSH spokesperson admitted that, even at the new REL of 1 mg per cubic meter of air, there may still be a significant risk of contracting cancer as this allows the inhalation of tens of thousands of nanoparticles.

These REL recommendations do not have the force of law. Another federal agency, the Occupational Safety and Health Administration (OSHA), determines Permissible Exposure Limits (PELs) for workers exposed to hazardous substances. PELs are federal regulations and thus mandatory, but it is doubtful that OSHA will issue PELs for exposure to CNTs or other nanomaterials in the near future because it is at this point impossible to determine a "safe level" of exposure to CNTs.

For comparison, a NIOSH speaker mentioned that Bayer, a large European-based manufacturer of CNTs, has set an occupation exposure limit (OEL) of 50 mg per cubic meter of air, and the OEL set in Japan for CNTs is currently 210 mg per cubic meter of air.

Adverse health effects have been observed in exposure studies of both purified CNTs (i.e., CNTs with any metal catalyst removed) and unpurified forms even when exposure involved low doses. Similar effects were found in studies of carbon nanofibers. According to a NIOSH spokesperson, there have been:

- 17 animal studies of CNTs that concluded that exposure caused pulmonary fibrosis (i.e., scarring of the lungs similar to asbestosis).
- 29 studies that found that exposure caused pulmonary inflammation.
- Two studies that found exposure caused neurological inflammation.

Several speakers at the conference discussed the possibility that a traditional dose/response relationship may prove to be inadequate for examining the toxicity of nanoparticles, in part because exposure to a low dose of nanomaterials can still contain many nanoparticles.

One NIOSH spokesperson discussed the need for medical registries listing individual workers exposed to nanomaterials combined with medical monitoring of those workers.

NIOSH personnel inspected several U.S. facilities, including both primary nanoparticles manufacturers and secondary users of nanomaterials that generally had 20 employees or less, and found:

- Employees were often exposed to airborne nanomaterials when collecting or extracting nanomaterials and during the cleaning of equipment.
- Nanomaterials scooped out of containers resulted in the airborne release of nanomaterials as workers walked the open scoop from the container to the work area.
- Employees often wear only a paper mask for personal protection (which is inadequate protection). One half of employees wearing full respirators had incorrect filters installed.
- Some facilities had fume hoods in place (a fume collection device over a shelf or table, so that experiments involving toxic or unpleasant fumes or gases may be conducted away from the work area), but many used then incorrectly (i.e., shut them off or turned them on at the wrong times).
- Secondary users of nanomaterials generally had higher exposures to airborne nanomaterials—particularly those using nanomaterials in powdered form.

A spokesperson from NIOSH called for a focus on protecting workers from exposure to carbon nanotubes because preliminary evidence indicates that these may be carcinogens.

A researcher from the University of California, Santa Barbara discussed the results of a survey undertaken to determine, among other things, how nanotechnology firms are addressing several occupational safety and health issues. The survey interviewed the Chief Executive Officers or Presidents of the firms. Of the 78 responding companies:

- 45 companies (59% of respondents) were domiciled in the U.S. (over 15% were from Europe, over 24% were from Asia, and over 1% were from Australia).
- The majority of firms (65%) had fewer than 50 employees.
- Together they used and/or manufactured 15 different nanomaterials (most common were nanosilver, titanium dioxide, silica, zinc oxide, carbon nanotubes and gold).

The findings included:

- Only 46% of the companies had nano-specific environmental health and safety (EHS) programs.
- 13% of the companies had no EHS program at all.
- 62% of companies did not monitor occupational exposures.

Currently, researchers addressing occupational exposure to nanomaterials are generating more questions than answers.

- Less than half of the companies required workers to wear personal protective equipment (such as respiratory protection). Nearly 30% of the companies that did require personal protection only required dust masks.
- Nearly 30% of companies used vacuuming and sweeping to clean spilled nanomaterials. This is against NIOSH recommendations as this increases airborne concentrations of nanoparticles. Another 13% of these firms used compressed air to blow unbound nanomaterials off of work spaces.
- 63% of companies had not developed a specific nanomaterial waste program, and 37% of the companies did not treat waste nanomaterials as hazardous waste.

Generally, the survey found the larger the firm, the more likely it will have nano-specific environmental health and safety programs in place and will monitor workplace exposures. One possible flaw with the survey is that those CEO-level associates may not actually know the day-to-day practices of line workers (i.e., a company president may require employees to always wear respiratory protection; workers, however, may not comply). The full survey is scheduled to be published by the end of 2011 or the beginning of 2012.

Occupational research in other countries discussed at the conference included:

- A Dutch study examined 19 facilities including both nanoparticle manufacturers and secondary users of nanomaterials and measured indoor air for nanoparticles between 10 nanometers (nm) and 1,000 nanometers in size. They found that workers in up to 30% of these facilities were exposed to airborne nanoparticles.
- A French study found employees of a company that coated surgical instruments with silver nanoparticles (10 nanometers in size) were exposed to airborne nanomaterials while cleaning out equipment. The cleaning operation took two to three hours daily and involved sanding the equipment. It was noted that there was no special ventilation equipment present in the room where the clean out occurred.
- An ongoing UK occupational exposure study found some workers wore no personal protective equipment even when scooping, weighing or transferring nanomaterials.

Several researchers expressed concern about occupational exposures to nanomaterials even when nanomaterials are encapsulated in a solid matrix particularly under abrasion scenarios (e.g., cutting, grinding and/or sanding). These operations may expose workers performing such operations not only to the released nanomaterial, but also to matter attached to the nanomaterial, such as bits of composite. Certain nanoparticles that are reactive or sticky may attract other matter in the environment, such as bacteria and dust.

Inhalation of nanomaterials during coating operations was also cited as a concern. Additional concerns were expressed for workers outside of primary nanomanufacturers and secondary users of nanomaterials. One study found that carbon nanotubes in an epoxy added to a surface area became airborne after 43 days as cleaning/abrasion wore down the epoxy. Wear testing of applied coatings containing nanomaterials seems essential to minimize this exposure.

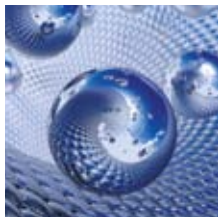
Nanomaterials in University Laboratories

An increasing number of universities are setting up nanomaterial research laboratories and providing academic courses on nanotechnology. A speaker from the University of Minnesota, which boasts several nanotechnology labs on campus, discussed safety and health concerns in this environment.

University labs often have a student workforce, which may include high school advanced placement students. Therefore, those working in university labs have a different level of experience than corporate labs regarding nanoliteracy and safety and health issues.

Little may be known about nanomaterial characterization and toxicity at the university lab level. It is not uncommon that nano-sized materials are treated the same as their bulk counterparts. There may also be a false comfort that small experimental doses used in the laboratory setting could not be hazardous. According to the speaker, these attitudes may also be present among staff researchers—not just the students. Safety and health rules at university labs may be considered a hindrance or an inconvenience. In some university labs, staff researchers are of the opinion that no personal protective equipment is necessary. Others may issue students working with nanomaterials only paper masks for respiratory protection. Of course, university labs may also have funding constraints that may interfere with the ability to provide the proper safety and health mechanisms and equipment.

All of this leaves students and staff researchers particularly vulnerable. Students, in particular, move on, either before graduation (e.g., drop outs, transfers) or after graduation. Currently no mechanism tracks those who worked with nanomaterials in university labs to see if they develop any latent health effects in the future. The speaker called for a national registry of student and staff university lab workers who have been exposed to nanomaterials.




Environmental Safety and Fate of Nanomaterials

A representative from CLF Ventures, an affiliate of the Conservation Law Foundation, discussed the need for additional research into the life cycle assessments of nanomaterials and products containing nanomaterials. Traditional life cycle assessment methods may be difficult to use when analyzing nanomaterials due to a lack of data and understanding of nanomaterial behavior in the environment. Apparently, this has yet to be the focus of much research.

New Exposure Studies

The results of dozens of new studies were presented at the conference. Several are highlighted here.

New studies have determined that the smallest nanomaterials gather in the nasal region situated in close proximity to the brain. Larger nanomaterials (in the 20–30 nanometer range) gather in the lungs. One study found that manganese nanoparticles measuring less than 20 nanometers traveled from the nasal area into the brain.

A recent study by researchers from the U.S. National Institute of Standards and Technology concluded that inhaled titanium dioxide nanoparticles are genotoxic (i.e., damage DNA or cause chromosomal mutations), but was unable to determine if it is a carcinogen.

Another presentation by researchers from Northeastern University deemed that nano-sized titanium dioxide, CNTs, gold nanoparticles, carbon fullerenes and carbon black were all genotoxic—although the body may be able to partly repair some of the damage over time. Exposure to single-walled CNTs, fullerenes (carbon molecules with a roughly spherical shape) and carbon black resulted in double-strand breaks in DNA which likely could not be repaired over time.

Recent studies out of Japan found that:

- Exposure to multi-walled carbon nanotubes (MWCNT) caused mesothelioma. This new study confirms several previous studies that reached similar conclusions.
- Exposure to carbon nanotubes (CNTs) resulted in pieces of CNTs lodged in the liver, spleen, kidney and lymph nodes—possibly brought to these organs via the bloodstream.
- In-utero exposure to nanoparticles of titanium dioxide altered gene expression in the brain and urinary tract of fetuses and may affect renal function of offspring.
- Nanoparticles of titanium dioxide traveled from the nasal area to the brain and resulted in cell death, which may lead to an increase in certain nerve diseases.

A recent study from Italian researchers found that:

- 50-nanometer silica nanoparticles coated with cadmium lodged in the kidney caused cell death and disruption of cell regulation and the membrane transport process. The study also found that nanomaterials 20 nanometers in size lodged in the trachea.

A recent study from Tunisia found that:

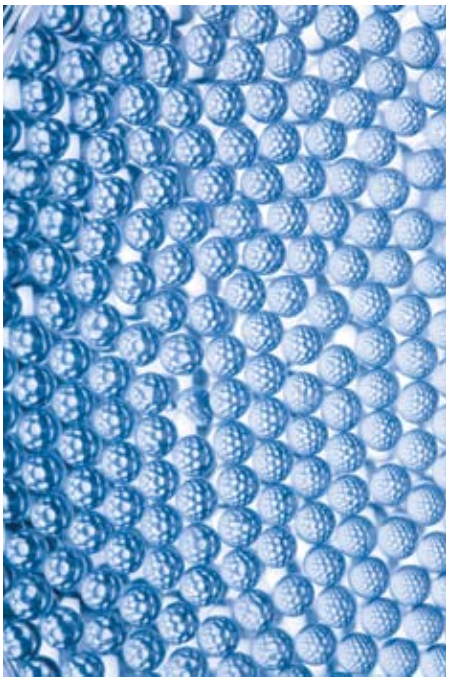
- Quantum dots (a type of nanoparticle) containing cadmium altered the semiconductive behavior of the sciatic nerve.

A recent study from researchers in the United Kingdom:

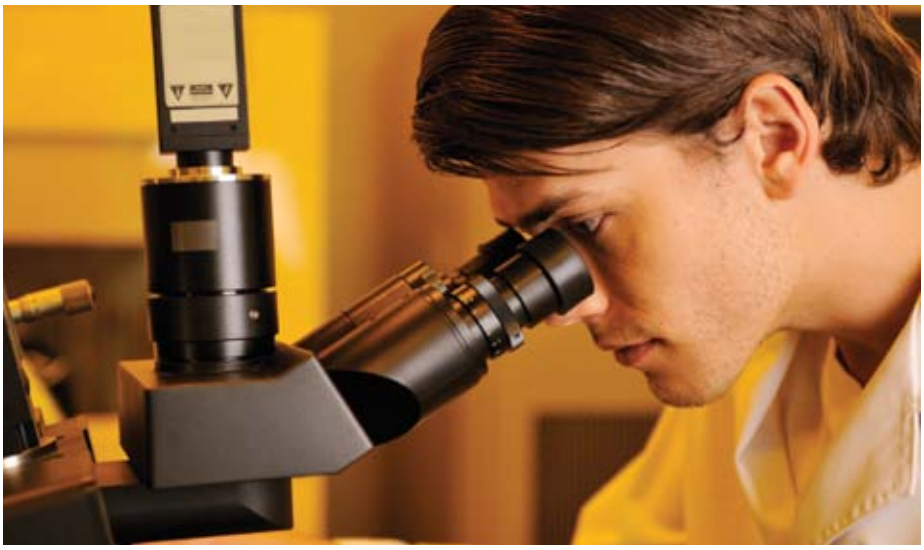
- Examined different types of CNTs (including single-walled, multi-walled and spun) and found that most were durable in the body and exhibited varying levels of toxicity.

Since this conference, several new nanotechnology developments and studies have been published. The results are highlighted below.

- A study by researchers from Indiana University-Purdue University Indianapolis found that exposure to even low concentrations of carbon nanoparticles penetrated kidney cells.[1]
- Researchers from the University of Plymouth found that nano-sized titanium dioxide particles caused vacuoles (holes) to form in parts of the brain and killed nerve cells in the brains of fish.[2]
- "There are about 20 nanomedicines on the market today," according to Mustafa Akbulut, an assistant professor of chemical engineering at Texas A&M University. He estimates that about 110 more are in clinical or preclinical studies. But little is known about how nanomedicines behave in the environment. In rodent studies, researchers have found that some of these drugs get excreted in the urine. If the same is true in people, nanomedicines could get into groundwater and soils through sewer systems."[3]



There may also be a false comfort that small experimental doses used in the laboratory setting could not be hazardous...these attitudes may also be present among staff researchers—not just the students.



Advances in nanomaterial science, and inclusion of nanomaterials into other products, continues at a rate that belies the economic recession.

- As mentioned earlier in this article, some nanomaterial manufacturers have stopped referencing the materials they produce as "nano," opting instead for the term "ultra-fine particles." "Three recent studies by researchers from the University of California, Davis have added to the growing body of data, suggesting that very fine and ultra-fine airborne metal particles are closely linked to serious human-health problems, including heart disease...These studies yielded unique epidemiological data supporting a growing body of evidence from laboratory and medical studies, which strongly suggests that very fine and ultra-fine metal particles are damaging to human health," said Thomas Cahill, a professor emeritus of physics and atmospheric sciences. "These tiny metal particles penetrate deep into the lungs and the cardiovascular system, damaging arteries and the heart itself."[4]
- Scientists at the Centre of Cancer Biomedicine at the Norwegian Radium Hospital are the first to show that uptake and accumulation of nanoparticles in cells can disrupt important intracellular transport pathways. The researchers discovered that nanoparticles in the size range of 20 nm—100 nm in diameter "interrupt the transport of vital substances in and out of a cell, causing undesirable changes in the cell's physiology and disrupting normal cell functioning."[5]
- A new study by researchers at Brown University found that nano-sized particles of nickel may give premalignant tumor cells a head start towards malignancy. The study found that larger particles, above the nano-scale, did not cause the same reaction. The data also showed "a difference in how nickel nanoparticles and nickel oxide nanoparticles react with cells. Nano-sized nickel oxide particles are so lethal that the cells exposed to them died quickly, leaving no opportunity for cancer to develop. Nano-sized metallic nickel particles, on the other hand, were less likely to kill the cells, but did contribute to the advent of cancer." [6]

Advances in nanomaterial science, and inclusion of nanomaterials into other products, continues at a rate that belies the economic recession. It may be reasonable to assume that those risks involving occupational exposure to nanomaterials, i.e., manufacturers of nanomaterials and workers in secondary industries using nanomaterials would be among the first to see any evidence of adverse health effects.

Considerations for Insurers

Court interpretations of Workers' Compensation statutes may make occupational exposure to nanomaterials more onerous for insurers providing coverage in certain jurisdictions. For instance, in September 2011, a Missouri appellate court ruled in a mesothelioma case that the state's Workers' Compensation statute covers *only* injuries arising from an "accident." This narrow interpretation of the statute would seem to open the door to lawsuits against employers over occupational disease claims.

It could be, however, that other susceptible populations could be first affected. Given that children are exposed to nanomaterials in a variety of products, and because they are often more vulnerable to the effect of toxins, it could be that specific latent illnesses may develop here first.

Any ensuing toxic tort litigation arising from nanomaterial exposure would likely cast a wide net for defendants that could include: the nanomaterial manufacturer, distributors of the nanomaterials (particularly if the manufacturer is a foreign company), secondary users that incorporated the nanomaterials into other products that may have resulted in exposure, distributors of products containing nanomaterials produced by foreign makers, and retailers of secondary products containing the nanomaterials.

Many of these risks are routinely written on occurrence-based policies with defense costs in addition to the policy limits available. In jurisdictions that have adopted an exposure trigger or the continuous trigger in toxic tort litigation, insurers could face limits stacking over multiple policy years.

Hopefully, the vast majority of different nanomaterials already created and in use will be of great benefit to society with only

a small percentage ultimately causing adverse health effects. Much remains unknown; however, there are now enough studies associating exposure to adverse biological impacts to make insurers wary. Exposure to certain nanomaterials has already been shown to cause asbestosis-like symptoms and/or mesothelioma—two illnesses that have already cost the property/casualty insurance industry tens of billions of dollars. These results should serve as a big red flag.

Insurers providing Workers' Compensation, Commercial General Liability, Products Liability and/or Commercial Umbrella coverage may wish to assess their potential exposure across their book to the potential for latent illnesses arising from exposure to nanomaterials. Carriers might consider adding application questions enabling them to discern the manufacture, distribution or use of nanomaterials. ISO (Insurance Services Office) has published class codes for nanomaterial manufacturers (53953) and for nanomaterial distributors (13208). There is no coding that enables insurers to differentiate secondary manufacturers adding nanomaterials to products versus those producing the same or similar products without nanomaterials. Various industries, however, are known for their use of nanomaterials, and insurers providing coverage for risks in those industries could develop supplemental applications to assist in the risk selection and underwriting process.

Where nanotechnology is concerned, it may be time well spent to sweat the small stuff. ■

Charlie Kingdollar is a Vice President in the Emerging Issues Unit of Gen Re's Treaty department. Charlie is responsible for tracking and analyzing developments that create new or changing exposures, and assessing their potential impact on insurers. Charlie speaks on Nanotechnology and other Emerging Issues at industry events across the country. He may be reached at 203 328 5756 or ckingdol@genre.com.

More on Nanotechnology

If you are interested in learning more about Nanotechnology, Gen Re published a background piece in 2004. Just ask your Gen Re representative to send you the PDF!

Endnotes

1. "Nanoparticles May Cause Kidney and Brain Damage," *Forbes,* 9/20/11.
2. Ibid.
3. "Nanomedicines Stick to Cellulose," *Chemical and Engineering News,* 9/11.
4. "Air-quality researchers tackle health implications of ultra-fine particles," UCDavis New Service, 9/3/11.
5. "Nanomaterials Can Disrupt Cell Function," *Science Daily,* 8/24/11.
6. "New study finds that exposure to nickel nanoparticles may contribute to lung cancer," *Nanowerk News,* 8/11.

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- The Regulatory Challenges Ahead—*The Bulletin,* September 2011
- Wind and Solar Energy Time Element—More Than Meets the Eye—*Facultative Matters,* August 2011
- Emerging Exposures and New Wordings—Are Your Forms Keeping Up?—*Policy Wording Matters,* June 2011
- Workers' Compensation—Managing Through Tough Times (and Not Just Living Through Them)—*Gen Re Viewpoint,* June 2011
- First Medicare Reimbursement Test—No Insurer Bad Faith Found—*E-News Multiline,* June 2011
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