



Investor Environmental Health Network

HEALTHY PEOPLE...HEALTHY BUSINESS

October 21, 2008

Secretary
Securities and Exchange Commission
100 F Street, NE
Washington, DC 20549-1090.

Subject: Comments on SEC Roundtable and 21st Century Disclosure Initiative
File Number 4-567

Via e-mail to rule-comments@sec.gov File Number 4-567

To Whom It May Concern:

I am writing as counsel to the Investor Environmental Health Network (IEHN), a collaborative partnership of investment managers focused on the risks and opportunities associated with toxic materials in products. Our members have approximately \$41 billion in assets under management. Thank you for this opportunity to comment on the Securities and Exchange Commission's 21st Century Disclosure Initiative.

The investors in IEHN are concerned with the financial risks and opportunities posed by the presence of toxic materials in the supply chain of their portfolio companies. Our experience and analysis indicates that the existing disclosure system is not working to address these issues. Awareness of product toxicity issues, and the adoption of safer materials, has led a number of companies to produce excellent financial results by anticipating and acting on long term financial risks of liability and market or regulatory exclusion, as well as the opportunities presented by being early adopters of alternative materials. In contrast, a larger number of other companies are currently failing to disclose or act on the immediate to long term risks posed by toxic materials, which we believe places some of them at serious financial risk. These shortcomings were highlighted in our recent report, *Toxic Stock Syndrome*, which found widespread failures to disclose relevant information. The report is also available on our website at <http://IEHN.org>.

We note in particular the importance of strengthening key *narrative disclosure requirements* in financial statements and SEC filings. As the SEC moves forward to reform its disclosure requirements, we hope you will address the issues raised by our report and comment letter.

Comments of Counsel, Investor Environmental Health Network SEC 21st Century Disclosure Initiative

1. Disclosure system must reflect a better balance of long and short term investor interests.

The current SEC disclosure framework is skewed toward encouraging disclosure of short term issues while underemphasizing the long term. Since many investors hold stock for the long term, it is essential that major issues that will play out in the long term be identified and managed. As has been noted in recent work by the Aspen Institute, the Conference Board, and the Marathon Club, there is a growing sense within the investment community of a need to align public policy and investment strategy to allow investors to weigh longer term returns, not just quarterly and annual returns.

Changes in SEC disclosure requirements can help to eliminate the skewed managerial incentives caused by current requirements. Disclosure of issues and numbers in financial statements affects investment decisions, but it also affects the management of the underlying issues. When reporting entities are required to disclose and characterize longer term issues, they are also more accountable to investors for how those issues are managed.

2. Rule changes are needed to address *narrative disclosure of additional ESG data points.*

Based on our review of SEC filings, including detailed analysis of individual company annual reports for 2006 and 2007, major industrial and other sectors affected by product toxicity risks are doing a poor job of informing shareholders of market risks they face due to toxic chemicals in their products.

Our enclosed report, *Toxic Stock Syndrome: How Corporate Financial Reports Fail to Apprise Investors of the Risks of Product Recalls and Toxic Liabilities*, was based on searches through thousands of SEC filings, and detailed review of more than 25 companies' reports. The report examines disclosures on: supply chain weaknesses before and after the 2007 toy recalls due to lead paint, scientific studies showing products causing asthma, potential health risks of nanotechnology, and the new European chemical regulatory program, "REACH" (Registration, Evaluation, Authorisation and Restriction of Chemicals).

Our analysis shows that the managers of these companies know much more about these product toxicity risks than they have chosen to share with investors. While the Management Discussion and Analysis is supposed to include trends, events and uncertainties known to management that may have a material impact on finances, when it comes to the issues underlying product toxicity concerns, this requirement is largely honored in the breach. SEC filers are not engaging in timely investor disclosure of financially important information on product toxicity risks. Some of the key findings of our report included:

Comments of Counsel, Investor Environmental Health Network SEC 21st Century Disclosure Initiative

- ***Bisphenol A.*** Bisphenol A (BPA), is a chemical found in polycarbonate baby and sport bottles and in canned food linings. None of the four major producers of BPA, or the many companies using these chemicals, had disclosed in their financial reports any awareness of the numerous scientific studies evidencing health hazards of this chemical.
- ***Toy recalls.*** Toy makers did not disclose what they knew about lead paint risks. Prior to 2007's recalls of leaded toys, neither Mattel nor Thomas the Tank manufacturer RC2 warned investors of a tide of Chinese product recalls dating back as far as 2001; Mattel's shareholder disclosures of lead paint problems with its own toys lagged by weeks internal company knowledge of such problems.
- ***Likely or possible European bans.*** Among 10 chemical company filings reviewed in detail, none provide meaningful quantitative data on the numbers of their products or proportions of sales that may be locked out of European markets under Europe's new, stringent chemical authorization requirements. Based on electronic review of filings in the SEC's database, the report demonstrates that most companies that sell products to Europe - from paint and cleaning products, to toys and cosmetics - appear to be glossing over or ignoring major requirements that go into effect this year to preregister the contents of their products in European markets.
- ***Asthma risks.*** Companies are not disclosing to shareholders the potential for their products to cause or exacerbate asthma. The report notes Dow Chemical and Procter & Gamble as two companies that sell products containing chemicals evidenced to cause or exacerbate asthma, and which are not disclosing these risks to investors.
- ***Nanotechnology.*** Manufacturers are not disclosing the evidence of health risks of nanotech products, or the lack of adequate product testing conducted prior to their sales. While some nanomaterials manufacturers disclose potential uncertainties, users of the materials in an array of products from electronics to cosmetics are not disclosing the potential health and financial risks, even though some of these products, known as nanotubes, have been found by scientists to resemble asbestos fibers in structure and respiratory health effects.

Recommendations: Based on these and other conclusions of the Toxic Stock Syndrome report we recommend refinements to the Securities and Exchange Commission disclosure policies. The SEC's reformed disclosure program should ensure that companies will:

- **report on credible new scientific findings indicative of potential product hazards, and post the company's own scientific responses and defenses only after clearly describing information on credible, adverse scientific findings.**

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SEC 21st Century Disclosure Initiative**

- **discuss and analyze recall and materials toxicity trends found in government regulatory databases, and their relevance to company supply chains and materials.**
- **promptly communicate, both internally and externally, information on supply chain management, including both specific problems as they emerge and any weaknesses in compliance assurance systems.**
- **characterize the portion of their product lines – as a portion of sales - that are Substances of Very High Concern (the products that may be banned or restricted in uses by European regulators). The potential for securing exemptions from the EU, given the high level of uncertainty regarding these outcomes, should not be a basis for avoiding providing this baseline analysis for product lines.**

In addition, we believe the SEC should create a working group to examine how to integrate ESG and sustainability reporting in its disclosure system. With a growing number of companies in the US and especially worldwide reporting on ESG metrics, it is essential that the SEC's disclosure system be able to accommodate ESG data.

3. SEC's new disclosure changes should restore investor recourse to request "risk evaluation" information through shareholder resolutions.

We believe the 21st Century Disclosure Initiative presents an opportunity to reconsider a trend in Securities and Exchange Commission staff decisions, denying shareholders the ability to file resolutions seeking "risk evaluation."

Since 2003, the SEC staff has issued a number of unfavorable rulings on shareholder resolutions because, according to the staff, the resolutions asked companies for an *evaluation of financial risks* associated with environmental, human rights or other issues that the SEC staff has decided to treat as excludable ordinary business. This trend in staff decisions dramatically limits the scope of previously acceptable shareholder proposals, and therefore curtails the rights and protections of investors to ask for the financial impact of significant environmental and social policy issues on companies.

While the staff is allowing shareholder resolutions that ask for reports on how a company's actions will affect the environment or human rights, it is ***not*** allowing resolutions that ask how any outside issues (such as climate risk, homeland security or the HIV/AIDS pandemic in Africa) may affect the financial performance of the company. Given that the latter is a core concern to investors, the "evaluation of risk" exclusions are undermining the clear interests of investors.

Our research shows that:

- The staff application of the "evaluation of risk" rationale is not consistent with SEC rules or historical practice;
- The staff has excluded proposals that were permitted in previous years;

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- The staff's use of the "evaluation of risk" rationale has grown steadily in the past few years and the rationale was used 13 times in calendar 2006;
- In calendar 2007, at least 10 proposals were excluded explicitly of evaluation on risk grounds and implicitly on another 14 occasions;
- The number of resolutions excluded is not a complete reflection of the impact of these rulings on shareholders, because the SEC rulings have forced many shareowners to rewrite their proposals to avoid requests for the financially relevant information that is now deemed excludible by the Staff.

A growing number of mainstream investors such as Goldman Sachs, Lehman Brothers and Citigroup acknowledge the materiality of environmental and social issues. Investors, industry analysts, and academics consistently point to the financial consequences of issues such as climate change, environmental management and employee health and safety in industry reports, during dialogues with companies and in the media. However, investors are currently unable to press for companies to report on these issues via one of the most important communication and disclosure tools available, the shareholder proposal process.

Therefore, in addition to the reform of disclosure rules, the Securities and Exchange Commission should in the course of refinement of its disclosure approach also restore shareholder rights and recourse to propose resolutions that seek an evaluation and disclosure of specific financial risks confronting a company -- the full array of risks, including contractual and marketplace issues, as well as environmental, social, and governance issues. This is an essential complement to the requirements of SEC disclosure rules, and is not contradictory or inconsistent with SEC reporting requirements.

Thank you for this opportunity to comment. We would be glad to participate in SEC roundtables or dialogues to further expound on any of these points.

Sincerely,



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TOXIC STOCK SYNDROME

How Corporate Financial Reports
Fail to Apprise Investors of the Risks of
Product Recalls and Toxic Liabilities

Sanford Lewis, Esq.

with

Richard Liroff, Ph.D. | Margaret Byrne, M.S. | Mary S. Booth, Ph.D. | Bill Baue

The Investor Environmental Health Network
A Project of The Rose Foundation for Communities and the Environment

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The Investor Environmental Health Network

www.iehn.org

**A Project of
The Rose Foundation for
Communities and the Environment**

www.rosefdn.org

The Investor Environmental Health Network is a collaborative partnership of investment managers advised by nongovernmental organizations. Through dialogue and shareholder resolutions, IEHN encourages companies to adopt policies to reduce and eliminate the toxic chemicals in their products. IEHN is a project of the Rose Foundation for Communities and the Environment.

The Rose Foundation for Communities and the Environment advances the principle that environmental protection and community regeneration must go hand in hand and are inextricably linked to a healthy economy. The Rose Foundation fulfills its mission through direct advocacy and grant making programs.

About the Authors

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Summary

During 2007, the sale of lead-tainted toys and toxic pet foods became major problems for toy and pet food companies, and prompted calls for overhaul and strengthening of federal consumer protection programs. **Beyond toys and pet foods, an array of products, ranging from water bottles to cosmetics, from mattresses to electronics, contain substances posing potential toxic hazards to consumers. These also present financial concerns for companies and their investors.**

The Securities Laws are intended to arm investors with information to effectively assess value and anticipate financial issues at companies they may invest in. This report evaluates whether existing financial disclosure requirements administered by the Securities and Exchange Commission (SEC) are working as intended to apprise investors of the most relevant and available data on these product toxicity issues.

Findings

While a few companies are relatively transparent regarding product toxicity issues in their financial reports or on their websites, if they even say anything at all, **most companies rely on boilerplate statements on compliance, while providing little or no specific information on risks and opportunities presented to the particular company.**

With regard to lead-related toy recalls, we found that **information was available to industry insiders in the years prior to 2007 to suggest that products sourced from China could contain lead paint.** However, the companies who were hit hardest, like RC2 and Mattel, disclosed little about these risks in financial reports prior to the 2007 recalls.

Looking toward the future, there are profound risks of product lock-out from European markets as a result of the new chemical regulatory framework known as REACH. Even though the initial requirements of REACH are operative this

Most companies keep their investors in the dark on product toxicity issues, using generic boilerplate statements with no information on risks to the specific company.

year, US companies disclose little about the potential impacts or their preparatory actions. A few chemical manufacturers, like Hercules, Inc. and Celanese, qualitatively disclose potential implications of REACH, but **none of the major chemical companies disclose what portion of their product lines will be under review for prohibitions under the REACH authorization requirements for Substances of Very High Concern.** Given that European manufacturing and sales can constitute a significant proportion of total business for US chemical companies like Dow Chemical, such omissions are troubling.

The REACH law does not only regulate chemical companies, it also has immense implications for companies that import other goods to Europe. A company that produces or imports goods is required to know and preregister chemicals foreseeably released from the products in ordinary use, or face the possibility of exclusion from EU markets. US companies that sell products to the EU need greater, more systematic knowledge of the materials contained in their products in order to comply with REACH.

Under REACH, companies like RC2 and Mattel, that suffered massive recalls for lead paint on toys, would have already needed to systematically understand what substances were in articles exported into the EU, in order to be compliant. Thus the underlying control systems needed for compliance with REACH may well have headed off the recalls of 2007.

However, strikingly few companies that sell regulated articles to the EU displayed any awareness of these implications in their financial report disclosures. This is consistent with a 2007 survey of companies by PriceWaterhouseCoopers (PWC) which found that 55% of US companies say that they have little or no awareness of the requirements of REACH. Most companies had not discussed the law with customers and suppliers to determine the impact on their supply chains. PWC concluded that US companies will “suffer significant business disruptions” as a result of their lack of preparedness. But no companies that we found are disclosing these significant business disruptions, even though this may include exclusion of noncomplying products from EU markets.

Similarly, issues that are currently known in the scientific literature regarding various health effects of chemical products are often ignored in companies’ financial reports. For instance, **major companies are not reporting to investors** on the potential financial risks or liabilities associated with emerging science linking materials in their products (certain liquid laundry soaps and pesticides) to **potential for causing or exacerbating asthma. Certain forms of nanotechnologies resemble asbestos in form and therefore pose potential health risks, yet even though these are being deployed in various consumer products, there is little to no disclosure of such information by companies deploying nanomaterials in consumer products.**

Methodology

We utilized the SEC’s Edgar database to examine whether various companies and sectors are disclosing product toxicity concerns. We examined the filings both with the hindsight of recent recalls, and with regard to future concerns such as European regulatory initiatives and emerging science. We examined the disclosures of at least 25 companies in chemical manufacture, toys, personal care products and other sectors. In many instances we also reviewed companies’ websites. We also conducted searches across the entire SEC database for relevant terms such as “nanotubes,” “asthma,” “lead paint” and “REACH” in particular sector groupings and tallied the results.

Recommendations

Companies must do a better job of disclosing product toxicity issues to their investors:

- **Companies should follow the leadership models from social issues auditing and reporting to provide added information on chemical supply chain issues, including sources of materials, risk areas, and control systems.**
- Even under existing SEC disclosure rules, companies can disclose more useful information and clarify that they are interpreting their disclosure duties in a manner that is intended to give investors more information rather than less.

Institutional and individual investors in sectors such as chemicals, cosmetics and personal care products, home furnishings, and electronics need to request better disclosure from companies—through direct correspondence and support of shareholder resolutions seeking such disclosure. There are several resolutions pending in the Spring 2008 shareholder season that seek better product safety

disclosures—at Mattel, Dow Chemical, Avon, Kroger and Circuit City, among others.

The Securities and Exchange Commission should improve its guidelines to companies on these issues, including issuing new guidance or enforcement policies requiring companies to:

- **Discuss and analyze recall and materials toxicity trends found in government regulatory databases**, and their relevance to companies' supply chains and materials.
- **Promptly communicate, both internally and externally, information on supply chain management, including both specific problems as they emerge and any weaknesses in compliance assurance systems.**
- **Characterize the portion of their product lines—as a portion of sales—that are Substances of Very High Concern, the products that have to be authorized for continued uses in Europe under the REACH regulatory program.** The potential for securing authorization from the EU, given the high level of uncertainty regarding these outcomes, should not be a basis for avoiding and disclosing this baseline analysis for product lines.
- **Report on credible new scientific findings indicative of potential product hazards**, and post the company's own scientific responses and defenses only after clearly describing information on credible, adverse scientific findings.

Background: Financial Exposures From Toxic Products

Litigation Risks

Asbestos is one chemical that typically comes to investors' minds when they consider toxic litigation risks. According to a report from the RAND Institute for Civil Justice, through the end of 2002 companies had paid \$70 billion in response to 730,000 personal injury claims, and 66 companies had been driven into bankruptcy by asbestos.¹

Lead paint litigation is another recent example. On February 22, 2006, shares of Sherwin-Williams fell as much as 22% following reports that a Rhode Island jury had found the company guilty of creating a public nuisance that was poisoning children.² Until that case, the company had been largely successful in lead litigation. The stock has largely recovered from its steep drop, and the jury verdict is still being contested, but the litigation cloud continues to hang over the company.

Pharmaceutical giant Merck's unfolding imbroglio over the once-popular painkiller Vioxx is another example. Once heralded as a wonder drug, Vioxx became linked with strokes and

announced in November 2007 a \$4.85 billion settlement with individuals alleging injury from Vioxx.⁴ Merck management has also been targeted in shareholder lawsuits alleging that management made false and misleading statements and failed to disclose information known to it on Vioxx.⁵ The \$120 billion New York State Common Retirement Fund has alleged that Merck's management "knew, yet failed to disclose, that a growing body of evidence demonstrated that patients who used Vioxx were at an increased risk of adverse cardiovascular reactions, including heart attack, stroke, and death."⁶

As scientific information emerges about other toxicants, investors may well ask which company may suffer from having been a leading user or producer of the chemical that becomes known as "the next asbestos." As detailed later in this report, there are reasons to believe that some particular nanotechnology materials (nanotubes) may well qualify as the next asbestos. However, by reading the corporate disclosures of companies that use the materials in question, one would be hard pressed to know which companies are using the nanotech products, or whether the management is cognizant of the special risks involved.

Vioxx litigation led to a \$4.85 billion proposed settlement by Merck.

heart attacks. Merck withdrew it from the marketplace in September 2004. As of June 30, 2006, Merck reported it faced 14,200 lawsuits over Vioxx.³ As soon as the bad news started to hit the press in 2004, Merck's stock began to dive and investors saw the value of their Merck stock shrink 40% for the year. The company

Market Exclusion Risks: Regulation, Reputation, Consumer Demand

Products containing potentially harmful chemicals may be excluded from markets by regulation or by consumer preferences. A failure of a manufacturer to anticipate these developments can lead to costly marketplace exclusion. Increasingly, regulation in Europe and legislation being enacted by various states in the United States target specific chemicals for exclusion from the marketplace. Materials that are being targeted include, for example, brominated

flame retardants, certain heavy metals in electronics products, and phthalates in cosmetics and toys.

The failure to anticipate and disclose potential market exclusions may be symptomatic of a company holding onto its materials choices despite emerging scientific evidence of health risks. This has been true, for instance, for chemicals like DuPont's PFOA-based chemicals, and in the widespread use of phthalates in toys and other vinyl products.

In some instances, the manufacturers may simply be ignorant of the chemicals in their products. Nevertheless they may still suffer the consequences. For example, during the end-of-year holiday season in 2001, Netherlands authorities banned the sale of Sony PlayStation consoles because the cadmium in accessory cables exceeded regulatory limits. Sony lost sales, and costs to rework their product totaled about \$150 million. This episode prompted Sony to carry out a systematic supply chain and internal management review to prevent similar problems from occurring and to prepare for stricter regulations in the future.⁷ Sony's nimble response to this "lump of coal" in its 2001 Christmas stocking also stands as an example of how a company

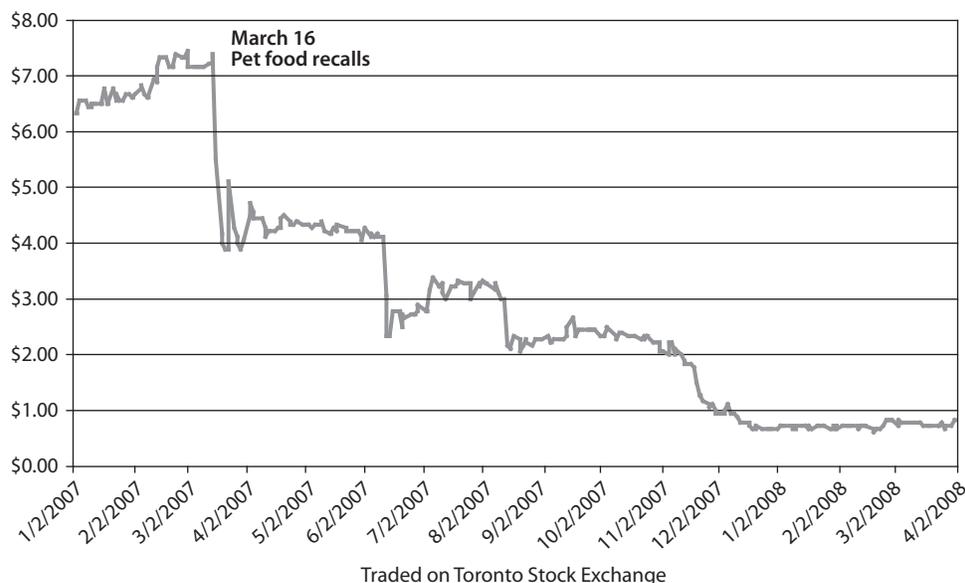
can learn from a toxic mistake and position itself to avoid costly repeats.

Another form of exclusion involves corporate reputational damage. Commonly referred to as "headline risk," the negative publicity garnered

The pet food recall damaged brand trust. One out of six pet owners saw their brands recalled; half of those experiencing recalls said they do not plan to return to their old brand.

by various pet food companies and toy companies in 2007 sometimes took a bite out of market share. To give one example, consider the massive pet food recalls of 2007. In 2007, pet food contaminated with melamine and rodenticide entered the US marketplace. Health repercussions led to a recall of hundreds of brands of dog and cat food nationwide. In the first 10 days of the recall, 471 cases of pet kidney failure were reported, with 104 of those pets dying, according to the Veterinary Information Network.⁸

Menu Foods Stock Price at Daily Closing



An online database for pet owners reported 3,600 deaths as of April 11, 2007.

Overall, several major companies recalled more than 5300 pet food products. The majority of recalled food content traced back to ingredients from a single company, Menu Foods of Ontario, Canada, but led to recalls of nearly 100 brands of cat and dog food. Other companies affected by the recalls included Sunshine Mills, which recalled 20 brands of dry dog biscuits, Nestlé Purina PetCare, recalling all sizes and varieties of Alpo "Prime Cuts in Gravy," and Del Monte, with 12 brands of cat and dog snacks.

Menu Foods reported losing at least \$42 million from the costs of the recall, even without taking

into account reduced sales.⁹ Pet food companies are facing lawsuits, lost contracts, and customers whose trust in them has been broken. Pet food manufacturers are not only losing money because their product is tainted; their relationships with customers are marred with distrust. Some premium brand pet food producers suffered extra reputational damage when they were revealed by the recall to use some of the same ingredients that economy chow makers use; once-loyal customers were reported to say that they would not return to their former brands.¹⁰ A poll of 1,000 Americans found that of the one out of six pet owners whose brands were recalled, nearly half said they did not plan to return to their old brand, even after the crisis has passed.¹¹

Background: Duties Of Disclosure

The Securities Laws have a goal of ensuring that information known to the management of a company is made available to investors through mandatory corporate financial reporting. Product toxicity information presents a classic example of the need for such regulated corporate disclosure, because the amount of “inside” information on these issues available to corporate managers is much greater than that available to “outside” investors. Corporate managers are likely to be aware, for instance, of recent scientific findings indicating potential health risks associated with their product lines or impending concerns that may lead to recalls; they are also likely to know which of their product lines are affected by these concerns. Management is not obliged to disclose all they know; their duty of disclosure is limited to “material” information, i.e., information that might affect a decision to buy or sell a stock.

In the course of proper corporate operations, the management of companies must necessarily gather and evaluate information on trends in product toxicity, recalls, and rules and legislation pending in relevant markets, and assess the factors that relate these issues to the potential effects on the company’s product lines. By contrast, an investor is likely to be dependent on articles carried in the mainstream press, and on whatever disclosures the company makes in its financial reports or other venues such as its web pages. In the absence of enforced legal obligations for disclosure, there are incentives to minimize disclosure of product toxicity concerns in financial reports. In the absence of uniform rules or shareholder understanding of the value of better transparency, stronger than typical disclosure by a company that reveals its genuine vulnerabilities (albeit, vulnerabilities that are shared with its competitors) could

drive down perceived value and therefore stock prices.

Although the Securities Laws require disclosures on liabilities such as product toxicity, the resulting disclosure is affected by management interpretation, including judgment calls that lead to information exclusion even when its disclosure would be beneficial to investors.

For instance, disclosure to investors of trends and uncertainties with material implications for a company’s future is mandated in the Management Discussion and Analysis (MD&A) of financial reports. The MD&A is a narrative discussion which is required to identify and analyze trends, demands, commitments, events and uncertainties that in the judgment of management are reasonably likely to materially impact a company’s liquidity, financial condition or operating results. In assessing what kinds of issues would be “material” and therefore merit disclosure, courts have stated that “there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information made available.”¹² Such would be the kind of information

Glossary of Terms

Form 10-K: Annual corporate report

Form 10-Q: Quarterly corporate report

Form 8-K: Current report, (for reporting developments between the quarterly and annual reports)

“Material” information: According to the courts, information that would alter the “total mix” of information and which might cause investors to change their decisions to buy or sell a stock.

that an investor would want in order to decide, for instance, whether to buy or sell a stock.

Where an item's ultimate financial impact on the company is shrouded in uncertainty, as is often the case with product toxicity issues, the SEC has established, but seldom enforced, a presumption in favor of disclosure. According to an SEC Statement issued January 2002, a matter should be disclosed in the MD&A unless the management has concluded that such item cannot reasonably impose a material impact on the company:

"Two assessments management must make where a trend, demand, commitment, event or uncertainty is known:

1. Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.
2. If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur."¹³

In applying this guideline to trends, events and uncertainties about product toxicity, several scenarios might lead to different interpretations of disclosure obligations. For instance, consider the trend of product recalls due to weaknesses in supply chain management in China. Is this reasonably likely to pose a material impact on the company's finances? In order to avoid disclosure, a company's management may wrongly make a leap of judgment, and broadly state – "our supply chain controls make this unlikely to affect our products." Similarly,

consider the "event" of impending regulations in Europe that may prohibit the sale of certain chemicals. Again, to avoid disclosure corporate managers may be leaping into the assumption that "our company will conduct risk assessments and be able to get an exemption from any eventual prohibition" (even though the rules are as yet unwritten).

As detailed in the case studies in this report, our review indicates that many companies are using assumptions like these to avoid giving investors the needed information for them to understand the risks involved for particular companies. In order to correct this tendency, the SEC would need to provide clearer guidance, as described in the concluding section of this report.

Other Securities Law requirements may also bear on disclosures of product toxicity issues, but to our knowledge have not yet been brought to bear in enforcement against specific companies. For instance, under the Sarbanes-Oxley Act, Section 302, and as adopted by the SEC, a company's principal executive and financial officers are required to certify that

"based on such officer's knowledge, the financial statements, and other financial information included in the report, *fairly present* in all material respects the financial condition and results of operations of the issuer as of, and for, the periods presented in the report..."

This requirement in the Sarbanes-Oxley Act is intended to ensure that companies do not use loopholes in existing SEC, Financial Accounting Standards Board (FASB) and American Institute of Certified Public Accountants (AICPA) guidelines to avoid disclosing items of substantial concern to investors. Under the SEC rule implementing the certification requirement, financial statements (including footnote disclosure), selected financial data, management's discussion and analysis, and other financial information should be considered when determining

whether information has been fairly presented.¹⁴

In addition, the SEC requires that if a statement in the company's reports leads to a certain inference, such inference should not mislead investors without further clarifying disclosures. SEC Rule 10b-5 provides that "It shall be unlawful for any person, directly or indirectly, by the

use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange...[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading...in connection with the purchase or sale of any security."

Anticipating Product Recalls

The toy recalls demonstrate concretely how companies in an affected sector may fail to disclose a significant trend. In hindsight, we can see the data foreshadowed the problems that emerged in 2007. The recall saga also shows how weaknesses in supply chain controls may be masked within the language of corporate disclosures.

Advance Warning of 2007 Product Recalls for Industry Insiders

Within the industry, there *was* advance warning to retailers and importers that lead-tainted goods were being manufactured in China. This information never translated into warnings to investors.

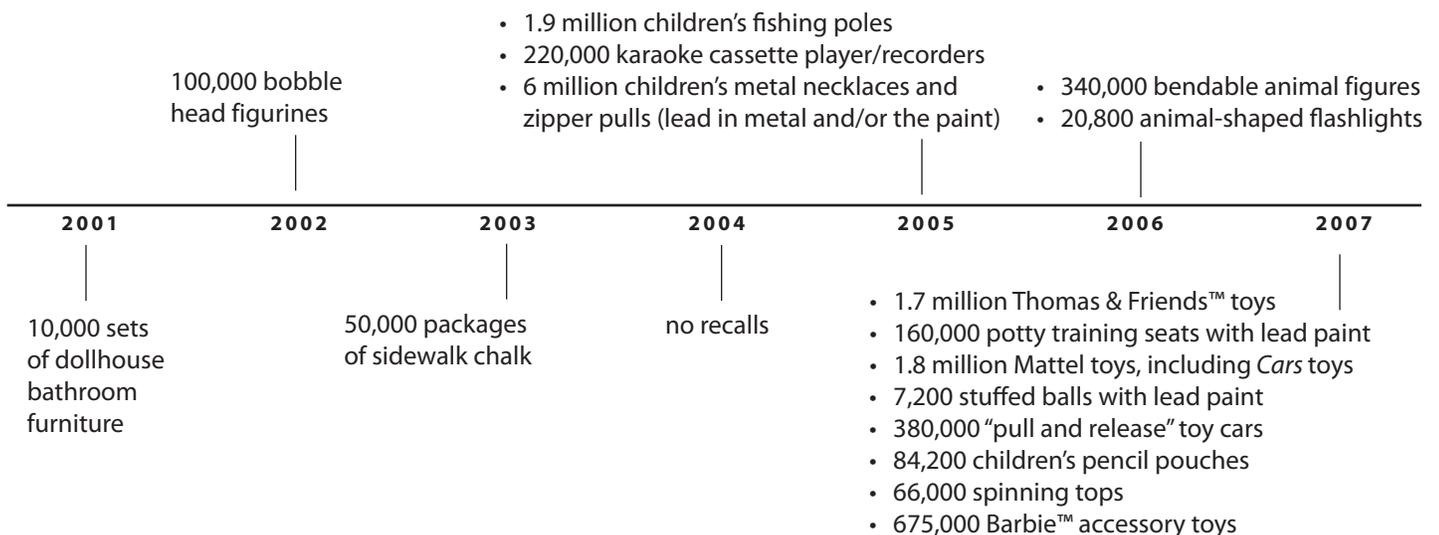
Product safety officials of any toy company would surely have been aware of the various lead paint related recalls for products made in China that began at least as early as 2000. The publicly available database at the Consumer Product Safety Commission (CPSC) shows growing problems with the recalls of toys tainted with lead at least as early as 2001.

Lead-paint recalls became so pervasive in 2007 that the CPSC posted a page on its website listing lead related recalls dating back to 2001, linking it to a “hazard search” engine with “lead” as a search category.¹⁵ A “lead” keyword query identified 26 lead-related recalls in 2007 before the first RC2 recall in June, 20 such recalls in

Within the industry, there *was* advance warning to retailers and importers that lead-tainted goods were being manufactured in China. But this information never translated into warnings to investors.

2006, 13 in 2005, six in 2004, four in 2003, three in 2002, and one in 2001. This list includes toy, clothing and jewelry components that contain lead, and many of the toy products involved were painted with lead paint in China.

Timeline: Lead Paint Related Recalls of Products Sourced in China



In 2001, 10,000 sets of dollhouse bathroom furniture were recalled because paint on the furniture contained lead. The furniture was distributed by Target Corporation and sold in Target stores nationwide. Its packaging clearly stated it was made in China.¹⁶ Then, in September 2002, 100,000 bobble head figurines sold at McDonalds were recalled because the paint on some of the figurines contained excess levels of lead. These figurines were imported by McDonald's Corporation of Oak Brook, IL, and Bobble Dreams USA of Fountain Valley, CA, and were manufactured in China.¹⁷ Lead-tainted paint on these items should have provided a warning that the supply chain in China was producing toxic goods.

Inexpensive jewelry marketed to children also contained this toxic material. In September of 2005, 455,000 units of lead-tainted jewelry made in China were recalled. This jewelry was imported by the Dollar General Corporation of Goodlettsville, TN, and was available in discount and dollar stores.¹⁸ Then, in November 2005, approximately 6 million children's metal necklaces and zipper pulls were voluntarily recalled by Stravina Operating Company, LLC, of Chatsworth, Calif. According to the CPSC, the recalled metal jewelry contained high levels of accessible lead in the metal and/or the paint. The recalled metal necklaces and zipper pulls were sold at discount, toy, party, grocery and drug stores from March 2002 through September 2005 for between \$2 and \$4. All of the jewelry was manufactured in China.¹⁹

The toxic trend continued in 2006. Small bendable animals distributed by Fun Express Inc., a subsidiary of Oriental Trading Company Inc, were given away by libraries nationwide as part of reading programs from January 2006 through August 2006. The CPSC issued a nationwide recall of 340,000 of these bendable animal toys because unsafe levels of lead were found in the paint used to decorate the toys, which were made in China for the Oriental Trading Company.²⁰ Interestingly, the problem was discovered and given national attention after a nurse

from Bloomington Hospital told a Monroe County (Indiana) librarian that the hospital found lead in the same toy in 2005, which the hospital had bought to give to children.²¹

This series of recalls from 2001 to 2006 was fair warning to any company that was importing goods from China. Arguably, any company with substantial imports from China had the infor-

The lead paint recalls from 2001 to 2006 were fair warning to any company importing goods from China. But the trend was not disclosed in the toy companies' reports prior to 2007.

mation needed to identify a "trend" that should have been disclosed to shareholders, namely the inability of various companies to control the amount of lead in paint; moreover, a thorough disclosure would also address the management's assessment of the adequacy of its own controls to prevent similar problems within its own supply chain. As described in the following case studies of RC2 and Mattel, this type of anticipatory disclosure was not performed by the toy companies suffering the worst during the flood of recalls in 2007.

**CASE STUDY:
RC2 Toy Recalls**

On June 13, 2007, CPSC and toy producer RC2 Corporation recalled 1.5 million Thomas & Friends™ wooden railway toys made in China with paint that contained excessive levels of lead, a powerful neurotoxin.²² Three months later, RC2 added 200,000 more Thomas toys to the recall,²³ including a toy that had been sent out as a free gift to children to apologize for earlier occurrences of lead in Thomas products.²⁴ Unfortunately, the company's woes were not over. In December 2007, RC2 recalled about

160,000 potty training seats made in China, again due to excessive lead paint.²⁵ RC2's Form 10-K annual reports have long included a standard paragraph on "Product Safety" stating that its "products are designed, manufactured, packaged and labeled to conform with [relevant] safety requirements...and are periodically reviewed and approved by independent safety testing laboratories."²⁶ However, the system described by that language failed to protect the company from a major problem with product safety.

The Company's Limited Disclosures

Failure to disclose that sourcing products from China presented lead paint and recall risks

Was RC2's supply chain group aware of the risks of lead paint in toys sourced from China? Did it increase monitoring and safety testing as the trend emerged from the year 2001? It is impossible to know from the company's 10-K filings that predate its own recall.

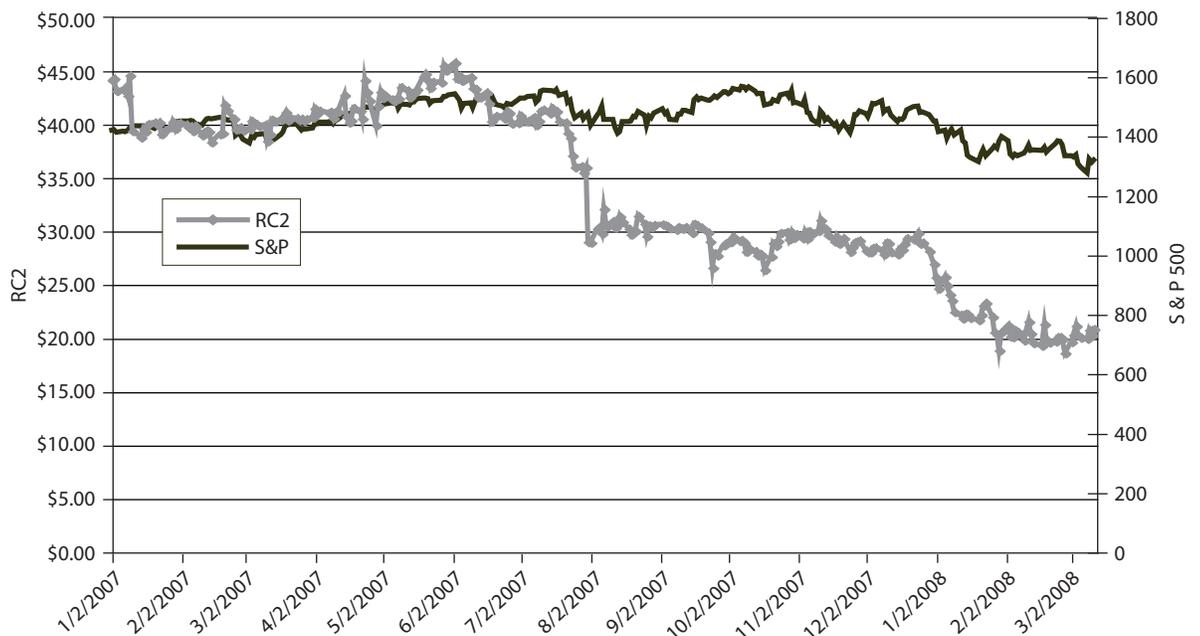
Although the CPSC issued 46 lead-related recalls from 2001 through 2006, 44 of which involved products geared toward children,²⁷ none of

RC2's SEC filings prior to its own recalls mentioned lead paint-related recall risks, instead discussing the potential for recalls generically, in boilerplate language. General language appeared in the 2002 Form 10-K that anticipated the potential impact of recalls, when a 137-word paragraph merely discussed how "Product liability, product recalls and other claims relating to the use of our products could harm our business."²⁸ The company expanded this paragraph slightly in its 2003 Form 10-K, and for the next three years maintained essentially the same standardized discussion of risks related to recalls.²⁹

Limited disclosures about supply chain management

Prior to its recalls, RC2 provided only general information in its disclosure documents regarding the degree of control it exercised over its supply chain. In 2006, almost all (91.8 percent) of RC2's products were manufactured in China, with almost half (47.9 percent) coming from RC2's seven third-party, dedicated suppliers who manufacture only RC2 products in eight factories, three of which are located in the RC2 Industrial Zone established in 1997 in Dongguan City, China.³⁰ That year, RC2 stated in its

RC2 and S&P 500 Price at Daily Close



Form 10-K that it employed 272 people in Hong Kong and China to “oversee the sourcing of the majority of our products. This group assists our suppliers in sourcing raw materials and packaging, performs engineering and graphic art functions, executes the production schedule, provides on-site quality control, facilitates third-party safety testing and coordinates the delivery of shipments for export from China.” The company stated in its 2006 10-K that “[a]ll products are manufactured to our specifications using molds and tooling that we own,”³¹ but that suppliers purchase raw materials such as paint. However, it did not discuss the known weakness in supply chains for such materials sourcing.

Following the identification of lead in its products, RC2 explained in its July 26, 2007 Form 8-K that an internal investigation pegged the lead problem to a limited number of paint colors purchased from an independent paint supplier and used at a single contract manufacturing facility, where RC2 terminated production and mandated controls preventing further purchases of the tainted product.³²

After the recalls, the company became more transparent as it attempted to manage the weaknesses in supply chain management. CEO Curt Stoelting outlined three steps the company was taking to address the problem:

- “Conducting rigorous audits of contract manufacturing facilities and their compliance with the Company’s quality specifications”;
- “Adding a new, tougher certification program for paint suppliers”; and
- “Increasing the scope and frequency of testing for both incoming materials and finished products, which now includes testing requirements on every batch of paint used in the manufacture of wooden toys.”³³

RC2 subsequently announced other components of what it called its “Multi-Check Safety System,” including:

- “Increased random inspections and audits of both manufacturers and their suppliers, including semi-annual audits and quarterly random inspections for key suppliers”; and
- “Zero tolerance for compromise on RC2 specifications reinforced by mandatory vendor compliance seminars and signed agreements.”³⁴

Was RC2 aware of the risks of lead paint in sourcing from China? It is impossible to know from the company’s filings that predate its own recalls.

Disclosures about costs and losses

Following the recall, a press release accompanying its July 26, 2007 Form 8-K revised the company’s estimated recall-related net charge for the second quarter of 2007 from about \$1-2 million to approximately \$4 million.³⁵ The release also anticipated an additional \$3-4 million recall-related net charges for the second half of 2007, an estimate repeated in its August 1 Form 8-K and its August 8 Form 10-Q discussing quarterly results.

“Any increase in the costs relating to the Recall would further reduce our net sales and profitability,” the company stated in its 10-Q.³⁶

The company also noted that a major asset at risk is the Licensee relationship with the company HIT Entertainment, which licenses the production of “Thomas and Friends” products. “In addition, addressing the Recall and issues relating to the Recall will likely divert management’s attention and resources from our business. The Recall may also harm our relationship

with the licensor who has granted the license under which we market the products affected by the Recall. Any termination of the License, or any adverse effect of the Recall on our relationship with the Licensor and the terms of our other licenses with the Licensor, may have a

None of RC2's SEC filings prior to its own recalls mentioned lead paint-related recall risks, instead discussing the potential for recalls generically, in boiler-plate language.

material adverse effect on our business and prospects and could reduce our profitability."³⁷ [emphasis added] As of February 2008, the RC2 company issued a press release noting that the Thomas brand was moving "full steam ahead" in 2008, which implies that its licensing arrangement with HIT Entertainment remains in place.

Disclosures about litigation

RC2's July 26, 2007 press release noted that the anticipated \$3-4 million net charge for the second half of 2007 included estimated defense costs related to the 12 class action lawsuits filed against the company. The company's August 7, 2007 Form 10-Q addressed this issue in more depth in a section captioned, "We face class action lawsuits relating to the Recall that could require us to pay damages or settlement costs or otherwise harm our business." While RC2 could not estimate potential damages and had not yet established financial reserves (it planned to do this in the second half of 2007), it anticipated a "material adverse effect" on business and profitability resulting from "unfavorable outcomes in these lawsuits, resulting in the payment of substantial damages."³⁸

In January 2008, RC2 announced a settlement of recall-related class action lawsuits filed in state courts on behalf of consumers, stating "In

connection with this settlement, the Company expects to record in the 2007 financial results, a charge in the range of \$3.5 million to \$4.5 million, net of tax, to cover estimated additional replacement costs or refunds, donations, notice charges, claims administration and legal fees related to this settlement."³⁹

In its 10-K for 2007 the company noted a loss of \$17.6 million, net of tax, or \$0.84 per diluted share, for the year ended December 31, 2007, related to the "recalls, based on the latest estimates of retailer inventory returns, consumer product replacement costs and shipping costs as of the date of this filing, as well as the additional replacement costs or refunds, donations, notice charges, claims administration and legal fees related to the settlement of the class action lawsuits."⁴⁰ The company also noted the potential additional impact on the company's reputation and future sales, but did not quantify that impact.

**CASE STUDY:
Mattel Toy Recalls**

Lead Paint and Mattel Toys

On August 2, 2007, the CPSC announced the recall by Mattel Inc. of nearly a million Fisher Price brand toys—including popular Sesame Street characters such as Elmo and Big Bird as well as Nickelodeon character Dora the Explorer—due to excessive levels of lead in the paint.⁴¹ The string of events leading here spanned half-way around the world, to the Lee Der Industrial Company in China.

According to testimony delivered by Mattel Chair and CEO Robert Eckert before Congress in September 2007,⁴² a series of tests were conducted leading up to the lead paint recalls.

Mattel investigators determined that Lee Der's tainted toys traced back to April 19 shipments from an unauthorized factory in Foshan City, China. This violated Mattel's safety standards, which require vendors to identify subcontractors

tors, their facility locations, and their paint sourcing standards. The standard helps to ensure that vendors (and their subcontractors) procure pigments only from Mattel Asia Pacific

Sequence of Events in Mattel Recalls

June 8, 2007	Testing by the independent laboratory Intertek revealed lead in the paint of toys. This prompted Mattel Product Integrity employees in Asia to stop shipment of the item and ask the manufacturer, Lee Der Industrial Company in China, to remedy the problem.
June 29	A test by Intertek found no evidence of lead in a sample of the same product line that was found to be contaminated in the June 8 test.
July 3	Intertek test of a different batch of the same product line from Lee Der came up positive for lead.
July 6	Additional Intertek test was positive for lead.
July 6	Mattel Asia Pacific Sourcing (MAPS) notified Lee Der it would not accept any more toys manufactured there.
July 9	Additional test further confirmed the July 6 results.
July 12	Mattel employees in Asia "notified senior management at Mattel of an issue with Lee Der products for the first time."
July 13	Mattel put a freeze on all shipments of suspect Lee Der products.
July 17	Mattel froze ALL products made by Lee Der and launched an investigation.
July 20	Initial Report to CPSC.
July 26	Full Report to CPSC.
July 30	Lead found in toy cars produced by different Chinese vendor, and different subcontractor.
August 1	Mattel detained distribution of <i>all</i> finished products made in Asia, in Mattel-owned factories <i>and</i> in factories of its 37 principal vendors.
August 2	Recall of nearly a million Fisher Price brand toys—including popular Sesame Street characters such as Elmo and Big Bird.
September 24	Recall of approx 750,000 additional toys made in China.
October 25	Recall of 38,000 more toys from China.

Sourcing (MAPS) qualified paint suppliers who test their pigments and certify that they meet safe content requirements, including lead standards.

However, this was not an isolated failure of the company's safeguards. Another product, "Sarge" die cast toy cars (from the Pixar film *Cars*), were found to contain lead on July 30. This product was made by a different vendor (Early Light Industrial Company of Hong Kong) with painting by a different subcontractor (Hon Li Da Plastic Cement Products Co. in Shenzhen City, China).

Mattel comprehensively tested the detained products, leading to the identification of yet more lead-tainted toys on August 9 and 11 that triggered letters to the CPSC on August 10 and 17 and a full report on August 27 requesting a fast track recall of three quarters of a million toys made in China that was announced on September 4. Mattel recalled an additional 38,000 lead-tainted toys made in China on October 25. The total number of recalled, lead paint tainted toys during 2007 to October 25 was approximately 1.8 million toys.

Mattel has been accused of failing to disclose product hazards on a timely basis to the government, consumers and investors.

Magnets and Misdesign

While lead paint posed an important example of product materials, Mattel faced even larger and more costly recalls due to misdesigned products containing high powered magnets that could fall off of toys and tear through a child's stomach lining if swallowed.

Beginning November 2006, the company began receiving consumer complaints about these magnets in various products and recalled two million Polly Pocket figurines; by Summer 2007 after

400 more reports of problems with other toy lines studded with magnets, the company was forced to recall an additional 18 million toys.

Allegations of Deferred Disclosures

Shadow Mattel

Mattel has been accused in several instances of failing to disclose product hazards on a timely basis to consumers and investors. The company was fined \$1.1 million by the CPSC for failing to promptly report a fire hazard involving its Power Wheels line of motorized minicars, designed to be ridden by children as young as two years old. Ten million of the cars were pulled from the market in 1998. The cars are alleged to have caused a number of fires in households or family garages. More recently, the company was alleged to have taken at least six months to report risks associated with small screws used in a farm-themed toy, despite gathering more than 30 separate incident reports about the issue, including one case in which a 14-month old punctured a lung by swallowing a screw.⁴³

The company takes the position that it should have the right to fully investigate issues before it discloses to the CPSC (and presumably to shareholders). Even though the CPSC requires reporting of hazards within 24 hours after the company becomes aware of them, the Chairman of the Board and CEO, Robert Eckert, asserted in a Wall Street Journal article that the company operates on its own timeline. This has meant in some instances allowing months of internal investigation to transpire before disclosure to the CPSC.

Disclosure of these product safety issues to investors has been alleged to also be on an inappropriately deferred basis. In a shareholder derivative lawsuit filed by the Sterling Heights Police & Fire Retirement System, the public pension fund of the police and fire departments of Sterling Heights, Michigan, plaintiffs allege that several Board members of Mattel sold \$33 million in shares from January through mid-

May, 2007 while the company deferred disclosure of the recent safety issues to investors and consumers. The suit alleges unjust enrichment by those board members, which would not have occurred if the company had disclosed on a timely basis. "The timing of these sales is highly suspicious," the complaint states, "given that the selling defendants sold their shares while Mattel possessed reports of defective products but before the defects were reported to the CPSC."⁴⁴

Lagging Disclosure to Investors

Although Mattel responded with prompt recalls as the severity of its lead contamination problems became known to headquarters, a review of the record shows that SEC disclosures lagged behind internal company knowledge by days and weeks. It is unclear whether these lags were due to poor internal company communication from personnel at Asian facilities to headquarters, or due to poor communications within headquarters between product safety and investor relations personnel.

Mattel disclosures on the issue of product safety prior to the recalls simply typically consisted of the statement at the bottom of company news releases cautioning on forward-looking statements, and stating that "the possibility of product recalls and related costs" were among the risks facing the company that could make current results not an accurate predictor of future financial outcomes.⁴⁵

On July 16, 2007, Mattel filed its Form 8-K with the SEC, reporting its 2007 second quarter financial results.⁴⁶ Absent from the filing and the more detailed press release accompanying it was any mention of the June 8 discovery of lead-tainted toys (more than a month before), the second test confirming the lead problem on July 9 (a week before), or the July 12 notification of senior company executives of the problem (four days earlier). It merely included the boilerplate list of potential financial risks, and the

press release simply mentioned “the possibility of product recalls and related costs,” without addressing lead, paint, or China.⁴⁷

The boilerplate list essentially condenses generic language from “Item 1A, Risk Factors That May Affect Future Results” in Mattel’s May 3, 2007 Form 10-Q quarterly report and its February 26, 2007 Form 10-K annual report, specifically echoing the heading, “Recalls, post-manufacture repairs of Mattel products, absence or cost of insurance, and administrative costs associated with recalls could harm Mattel’s reputation, increase costs or reduce sales.”⁴⁸

Despite the fact that some Mattel employees were certainly aware of lead paint related problems at the time of the July 16 press release accompanying its 8-K, the company did not inform its investors until August 2, when it filed an 8-K revising its second quarter pre-tax operating income down by an estimated \$30 million due to the lead paint recalls announced the same day.⁴⁹

“Although management is not aware of any additional significant issues associated with lead in paints used on its products, there can be no assurance that additional issues will not be identified in the future,” Mattel stated in its 8-K of August 2. The next day, the company issued a 10-Q quarterly report repeating these exact same words, as well as providing a more precise calculation of \$28.8 million total reduction to operating income for the second quarter of 2007. Yet Mattel CEO Eckert’s Congressional testimony acknowledged that on July 30 the company identified the “Sarge” toy car lead problems, leading to a quarantine of all products in Asia on August 1.

Mattel repeated the same “no assurance” wording in its October 26 Form 10-Q quarterly report through the third quarter of 2007.⁵⁰ Yet, the day before (October 25), the CPSC and Mattel issued a fourth recall. While the period covered in the 10-Q ended September 30, it

Mattel’s 2007 SEC disclosures on lead paint problems lagged internal company knowledge by days and weeks. Sometimes management published the statement that it was “not aware of any additional significant issues” several days after personnel had found serious issues.

believes credulity that the company was “not aware of any additional significant issues associated with lead in paints used on its products.” To say the least, it seems that this language did not closely track the state of knowledge on the next rounds of toxicity and recall issues.

The company disclosed that a number of suits were filed over the 2007 recalls and lead paint. Its October 26 Form 10-Q stated “Since August 7, 2007, seventeen lawsuits have been filed in the United States asserting claims allegedly arising out of the August 2, August 14, and/or September 4, 2007 voluntary product recalls by Mattel and Fisher-Price.”⁵¹

Anticipating Regulatory Impacts

Europe Enacts Sweeping Chemical Regulatory Programs

The array of chemical regulatory requirements in Europe provides an example of another area where corporate disclosure of issues with substantial financial impacts is uneven. SEC regulation S-K Item 101 requires a registrant to describe in its financial report the “material” effects that compliance with federal, state and local environmental laws regulating the discharge of materials into the environment will have on earnings, capital expenditures and the competitive position of the company and its subsidiaries.⁵² However, the Management Discussion and Analysis, provided by Regulation S-K item 303, requires more broadly that a company report on any known trends or any known demands, commitments, events or uncertainties that the registrant reasonably expects to impact various financial aspects e.g. sales, liquidity, capital resources. Thus while Item 101 might be understood to only apply to US laws, Item 303 would certainly apply to European laws if those laws reasonably may alter a significant market of a global company registered in the US, or impose substantial costs.

The European Commission (EC) has recently enacted a series of chemical regulations. These now define global best practices on toxics control laws. Combined, these laws paint a new chemical control landscape across all sectors—from cosmetics to information technology to pharma to retail. Unfortunately, to US investors the panorama may look more like a mostly-blank paint-by-numbers canvas, as company securities filings and other disclosures veil more than they reveal.

Some companies tell a detailed story in their annual reports of how the European laws may impact their operations, or at least the steps they are taking to bring themselves into compliance. Other companies, even some in deeply affected sectors such as Dow Chemical, scarcely mention the laws in their SEC filings. This range of disclosure practices undermines the needs of investors, who need to be able to consistently and accurately compare opportunities and impacts among companies and sectors.

The EU has been building momentum in recent years toward regulations that reduce product toxicity. The European Union Cosmetics Directive that was adopted in 2003 outlaws carcinogens, mutagens, and reproductive toxicants in cosmetics and personal care products. Now, the European Union continues to lead the global marketplace in identifying and banning toxic materials.

The RoHS (“Restriction of Hazardous Substances”) directive, which came into force July 1, 2006, bans six toxics—lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants—above mandated levels in new electrical and electronic equipment sold in the EU market.⁵³ The “Waste Electrical and Electronic Equipment” (WEEE) provisions, which require electronics makers and dealers to manage product toxicity through take-back, recycling, and responsible disposal programs, entered into force a year later (behind the scheduled August 2006 targeted launch).⁵⁴

Largest New European Chemicals Program: REACH

The preceding sector-focused regulations paved the way for the EU's largest chemicals initiative. In June 2007, the EU's massive program known as "REACH" (Registration, Evaluation, Authorization and Restriction of Chemical Substances) came into force, requiring chemical manufacturers and importers in the EU to document the safety of their products. REACH requires manufacturers and importers to gather information on the properties of substances that meet certain volume or toxicological criteria and register the information in a central database to be maintained by the European Chemicals Agency headquartered in Helsinki, Finland. REACH can also lead to requirements to end the use of some of the most dangerous chemicals (Substances of Very High Concern), particularly where companies cannot prove they are adequately controlled against harm, or that the benefits to society exceed their costs. The authorization provisions don't only affect chemical manufacturers—they also can affect any company that incorporates chemicals into products.

REACH preregistration requirements necessitate materials management by users as well as producers of chemicals

Under the REACH program there is an immediate obligation for companies to preregister chemicals produced or imported to the EU. From June through November of 2008, manufacturers are to preregister chemicals in existing products produced or imported in excess of one metric tonne per year. By December 1, importers and producers of items such as clothes, furniture, toys, etc. ("Articles" under the terms of the law) that contain the targeted chemicals also must be preregistered. A producer or importer of an article has to register the substance(s) within an article if the substance is intended to be released during normal or reasonably foreseeable conditions of use and if the total amount of that substance exceeds one metric tonne per year per producer or importer. Thus a company

selling pens to the EU needs to know what chemicals are in the ink, since that is "intended to be released." But a company selling toys which may release chemicals when a child places the toys in their mouth also could have a duty to preregister, as a chemical released during "foreseeable conditions of use."

For US companies selling to Europe, REACH necessitates much greater, systematized knowledge of potentially toxic materials in products.

Arguably, companies like RC2 and Mattel that suffered massive recalls for lead paint on toys would have had an obligation to preregister the lead paint on their products under REACH once the preregistration of articles becomes law (e.g. after December 2008). Therefore, these requirements have a profound implication for US companies that do business in the EU. A company that produces or imports the relevant products has to know and preregister the chemical content of those products. In the absence of preregistration, the products could be excluded from EU markets. Thus, for many US companies, REACH means that continuing to sell products to the EU necessitates much greater knowledge of the materials contained in the products, and a materials management system for tracking those contents.

REACH program authorization program targets known chemical groups

The chemicals targeted by the REACH authorization program include some specific, limited categories, referred to as "Substances of Very High Concern" (SVHC):

- 1) Known or suspected carcinogens, mutagens, or reproductive toxicants (CMR),
- 2) Persistent, bioaccumulative and toxic (PBT) chemicals,
- 3) Very persistent and very bioaccumulative (vPvB) chemicals,

- 4) Other chemicals that present concerns and serious effects, similar to the aforementioned categories.

For many substances, information is already available for a company to know whether their products would likely qualify as one of the first three these categories. Existing databases of known or suspected carcinogens, mutagens, or

A company selling toys that a child can place in his mouth could have a duty to preregister because of potential for release during “foreseeable conditions of use.”

reproductive toxicants (CMR) already list chemicals that would fall under point 1 (above).

The second designation of persistent, bioaccumulative and toxic is included in the REACH initiative because of the long-term impacts of these chemicals. The health and environmental effects of these chemicals are potentially irreversible and unpredictable in the long term. For example, persistent chemicals do not break down quickly in the environment, and bioaccumulative chemicals build up in a body or within a food web. When these chemicals also exhibit toxicity, the threat is especially serious. Policymakers have concluded that where chemicals are *very* persistent and *very* bioaccumulative (vPvB) as a matter of precaution they will not wait for proof of toxicity before deciding that environmental exposure should be curtailed.

In the case of both the second and third categories (PBT and vPvB), companies readily know or can easily ascertain whether their chemicals qualify as likely to be subject to authorization. Many chemicals have long been targeted by policymakers and NGOs for these qualities; the criteria regarding chemicals qualify for PBT or vPvB are spelled out in Annex III to the REACH legislation, and in many instances the relevant

tests have been conducted on the chemicals by the producers or their consultants to allow them to make the needed determination.⁵⁵

Even though companies may not have yet conducted a detailed analysis of persistence, bioaccumulation, or toxicity of particular compounds, structural analysis of the compounds can lead to the determination of whether they are likely to qualify. A voluntary online EPA program, the PBT Profiler, uses such a structural analysis to conduct a preliminary assessment of whether chemicals are likely to qualify as persistent, bioaccumulative, or toxic based on their standard Chemical Abstract Service (CAS) numbers.⁵⁶

In order to continue to market any of the SVHC chemicals, companies will need to obtain authorization by demonstrating either (1) that existing controls are adequate to prevent harm, or (2) that the socio-economic benefits of a product outweigh the costs or risks and there are no technically and economically viable alternatives. However, for many of the SVHC chemicals, due to their ability to bioaccumulate and the level of toxicity concern, the only option permissible under the law for authorization is the latter form, which requires showing cost exceeding the benefit and the lack of alternatives.⁵⁷

The law places administrative and implementation burdens on companies whose responses to these challenges will help determine their ongoing success not only in EU markets but in markets worldwide.

Preregistration Phase Requires Action Now

Companies have from June 1, 2008 until November 30, 2008 to preregister “Phase One” substances, which are products they already market in the European Union, or that have been imported or made in the European Union in the past fifteen years even if not sold there. The preregistration requires basic information such as the name of the chemical and the importer. According to an environmental counselor with the European commission, companies

Examples of Deadlines Under European REACH Law

JUNE 1 TO NOVEMBER 30, 2008

Pre-registration by chemical makers and importers of existing substances of 1 metric tonne or more per year

DECEMBER 1, 2008

Registration and notification of substances in articles

JANUARY 1, 2009

European Chemicals Agency publishes list of pre-registered substances

JUNE 1, 2009

European Chemicals Agency's first recommendation of priority substances subject to authorization

DECEMBER 1, 2010

Registration requirements for various chemicals and quantities

covered by this issue should be examining their stock of chemicals and the requirements of REACH at the present time. REACH will require chemical manufacturers to submit a chemical safety report for approximately one-third of chemicals on the market, those that are imported or produced in quantities greater than 10 metric tonnes per year.⁵⁸ This report must include information on how the chemical is used by downstream users, the industries that use the chemical in products, and the risks associated with different exposure scenarios.

Effects on Companies

Various analysts have examined the impacts of REACH on companies. Ethical Investment Research Service (EIRIS), a UK-based socially responsible investing (SRI) research firm, recently produced a report briefing investors on risks facing the chemical industry not only from REACH but also from other regulatory and societal developments. This report, entitled *Beyond REACH--Chemical Safety and Sustainability Concerns*, assessed the preparedness of seven publicly traded companies worldwide that produce specialty chemicals for sale in Europe and have "high exposure" to regulatory and market risks.⁵⁹ Peter Webster, executive director of EIRIS, stated, "The process of phasing dangerous chemicals out of the environment is clearly a major challenge for the chemicals industry. Although we discovered a number of examples of good practice, the general picture was of an industry not yet fully prepared for this challenge."⁶⁰

Financial analysts such as Innovest Strategic Value Advisors have concluded that small to midsize companies may bear the most substantial financial risk from REACH.⁶¹ However, for individual companies of all sizes, financial report disclosure is scant.

As a result of REACH, many US and global companies will have to choose whether to bifurcate their supply chains and manufacturing processes, maintaining one chain that complies with these new EU regulations alongside existing chains that are largely non-compliant, or integrating compliance across all their operations. The influence of REACH far exceeds the boundaries of the EU.

While REACH will have dramatic impacts on the ability of companies to do business in Europe, perhaps as significantly, REACH is setting the agenda for legislation in the United States, including both state level legislation and congressional initiatives. At least eight states are considering major chemicals reforms, with many of the initiatives in the states mimicking elements of the REACH law.

Evaluating Corporate Disclosures on REACH: Chemical Producers

We evaluated various chemical producers' disclosures regarding the impacts of REACH. While some companies discuss REACH and other EU directives in recent 10-K filings, others

ignore or gloss over this important topic. Most importantly, the disclosures have typically not revealed the extent to which companies sell or import chemicals that are likely to be in the REACH “authorization” group—i.e. what portion of their product lines the company is aware of that could be subject to exclusion from sale in Europe. Companies instead state that REACH regulation will not affect operations in the short-term but that long-term effects are uncertain, or they issue a generic comment that the law may have some unspecified impacts. Some companies state that they intend to demonstrate that their “authorization group” products do not present a public health risk. Other companies provide fragmentary information on this issue on their websites, but little or no information in their reports to shareholders.

Dow Chemical

For instance, Dow Chemical, which has 50 manufacturing locations in 19 countries, provides no information on REACH or its impacts in their financial report disclosures. According to one observer, a US-based toxicologist, Dow Chemi-

While some companies discuss REACH and other EU directives in recent 10-K filings, many more ignore or gloss over this important topic

cal company has at least 18 people hired to work on REACH.⁶² European markets represent 36 percent of Dow Chemical’s sales and 10 percent of the company’s assets, yet the company’s 2007 10-K filing does not discuss the potential impact of REACH.⁶³

The company does discuss the issue on its website, which states:

We intend to pre-register all of the eligible substances that we manufacture in the EU or manufacture outside the EU and import

into the EU within the required timeframe. We anticipate that the majority of substances in our current portfolio will be registered for a range of typical downstream uses.⁶⁴

With regard to the potential for Dow Chemical products to be prohibited under the authorization part of the law, the company simply expresses confidence that its products will not be prohibited:

We also expect that only a small number of the substances we manufacture will be subject to the authorization process for “substances of very high concern” under REACH. However, we expect that we will be able to demonstrate proper levels of risk management for supported uses of these substances.⁶⁵

To assess the impact of REACH, investors would need to know exactly which product lines are potentially at risk in Europe and the volume of sales of those product lines. Yet nowhere does Dow Chemical characterize which of its products are likely to be treated as substances of very high concern (which for many substances is now ascertainable based on the definitions under the law) and thus may potentially be prohibited under the new law. Given the current lack of discussion surrounding how REACH will materially affect companies, the SEC guidelines requiring disclosure in the case of uncertainty should apply – in other words, they should be erring on the side of disclosure.

Hercules Inc.

In contrast with Dow Chemical, another company with very substantial business in Europe did discuss REACH in its recent 10-K filing for 2007 in meaningful qualitative terms. Hercules Inc has 10 percent of its assets and 35 percent of its sales in Europe. This is a growing market for this corporation, with sales in Europe comprising 34% of total sales in 2005 and 37% in 2006.⁶⁶ In its management discussion and analysis the company wrote:

REACH, Regulation (EC) No. 1907/2006

On June 1, 2007, the European Union's regulations concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (commonly referred to as "REACH"), Regulation (EC) No. 1907/2006, became effective. This regulation requires manufacturers and importers into the European Union of certain chemicals to register those chemicals and to evaluate their potential impacts on human health and the environment. Under REACH, the continued importation into the EU, manufacture and/or use of certain chemicals may be restricted, and manufacturers and importers of certain chemicals will be required to undertake evaluations of those chemicals, including toxicological and ecological evaluations. The requirements of REACH are expected to be phased in over a period of years, and compliance with its requirements are anticipated to require expenditures and resource commitments by the Company, which could become material depending upon how various provisions of REACH are interpreted and implemented. It is also possible that REACH could affect raw material supply, customer demand for certain products, and the Company's decision to continue to manufacture and sell certain products.⁶⁷

FMC Corporation

The FMC Corporation, which is heavily engaged in European markets, notes the existence of REACH and the general fact that changing regulatory environments may affect sales. In its 10-K for the year ended December 31, 2007 FMC reports:⁶⁸

Changing regulatory environment

Changes in the regulatory environment, particularly in the United States and the European Union, could adversely impact our ability to continue selling certain products in our domestic and foreign markets. Our Agricultural Products business is most sensitive to this general regulatory risk. In the

European Union, the regulatory risk specifically includes the new chemicals regulation known as REACH (Registration, Evaluation, and Authorization of Chemicals), which will affect each of our business segments to varying degrees. The fundamental principle behind this regulation is that manufacturers must verify that their chemicals can be marketed safely through a special registration system.

It goes on to add:

We intend to defend vigorously all our products in the U.S. and EU regulatory processes.

However, the company does not include a detailed description of which segments are at risk, for instance, under the REACH authorization program.

Rohm and Haas

Like Dow Chemical, the 2007 Annual Report (filed February 28, 2008) for Rohm and Haas, a US company with very substantial business in Europe, had some of the scantiest disclosure on REACH of any company we examined. It did not mention or analyze the extent of impact of REACH on the company.

Despite the lack of information in their 10-K, the company's website did include an article⁶⁹ noting that in general the REACH program might have substantial impacts on the chemical industry. Andrea Sitia, product stewardship manager for Rohm and Haas Adhesives and Sealants in Europe, helps to predict these impacts:

Rohm and Haas Prepares for Compliance

Rohm and Haas is preparing thoroughly for implementation. The company maintains a dedicated REACH team, composed of members such as toxicologists and product integrity and regulatory specialists, that tracks developments daily. "We conducted an in-depth evaluation of how many substances

we use, import or manufacture in Europe that might be affected by REACH," Sitia explains.

The company recommends that its customers educate themselves soon. "In particular, understand final end-use applications for those products containing concerned substances," Sitia cautions. "The EU will authorize those substances only for specific end-uses in which risks are controlled, where the benefits outweigh the risks, and when no substitutes exist."

Customers also must prepare and plan for the costs associated with implementation and with supplying data such as use and safe handling methods. Many studies have assessed the expected economic impact of REACH across the entire European chemical industry over the first 11 years. Most estimate total compliance costs between two and four billion Euros, but the most alarming studies see costs as high as seven billion.

It is noteworthy that the article says that the company has conducted an evaluation of "how many substances we use, import or manufacture in Europe that might be affected by REACH." Yet the company—as is the general practice in the sector—has not provided information to investors on the portion of its product lines that it anticipates will be addressed by the stringent and potentially prohibitive Authorization phase of REACH.

Celanese

Celanese notes in its 2007 10-K that approximately 43% of its net sales were to customers in Europe and Africa.⁷⁰ With regard to REACH the company notes:

The Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH"), a chemicals policy, became effective in the European Union on June 1, 2007. REACH established a system to register and evaluate chemicals manufactured in, or imported to,

the European Union. Additional testing, documentation and risk assessments of various chemicals will occur across the chemical industry. Some chemical products may have to be taken off the market. As a result of REACH, we are likely to incur additional costs to test, document and register products used and/or manufactured by us. In addition, potential litigation arising from REACH may adversely affect our operations and financial results by imposing other additional costs on us and/or restricting our ability to import or export certain chemical products. Other pending initiatives will potentially require toxicological testing and risk assessments of a wide variety of chemicals, including chemicals used or produced by us.

Later the 10-K also notes:

The above-mentioned assessments in the United States and Europe may result in heightened concerns about the chemicals involved and additional requirements being placed on the production, handling, labeling or use of the subject chemicals. Such concerns and additional requirements could increase the cost incurred by our customers to use our chemical products and otherwise limit the use of these products, which could lead to a decrease in demand for these products. Such a decrease in demand would likely have an adverse impact on our business and results of operations.

Huntsman International

Huntsman International has also increased its preparations for REACH. Its 2007 10-K describes the company's role in complying with REACH, stating "The registration, evaluation and authorization phases of the program will require expenditures and resource commitments in order to, for example, develop information technology tools, generate data, prepare and submit dossiers for substance registration, participate in consortia, obtain legal advice and reformulate products, if necessary." The company has

also “established a cross-business European REACH team that is working closely with our businesses to identify and list all substances purchased, manufactured or imported by or for us into the EU.” The financial impact of REACH appears to be minimal at this time, the company having spent “approximately \$3.0 million on REACH compliance in 2007...we do not anticipate that compliance costs will be material to us in the near-term.”⁷¹

Arch Chemicals

Arch Chemicals addressed the toxicology testing required by REACH in their 2006 10-K, stating “while we generally expect that testing will support re-registration approval, it is possible that such testing will not or that those agencies will find the test results or supporting data unsatisfactory. In such a case, sale of some of our products may be restricted (or in the extreme case, banned) in the EU.”⁷² This brief statement was expounded upon and additional information was added in their 2007 10-K. In a discussion of risk factors, the report states “International sales and operations are subject to significant risk, including local legal and regulatory requirements, including those relating to the European Biocidal Products Directive, which requires biocide manufacturers, including the Company, to re-register their biocidal products for sale in the European Union (“EU”) and the EU’s Registration, Evaluation and Authorization of Chemical Substances regulation (“REACH”).”⁷³

The company characterizes REACH as both a potential liability and an opportunity to create competitive advantage. “The Company must understand the biological and chemical effects of its products and excel at both developing new products and finding new applications for existing ones. The Company has invested in upgrading and expanding its technical strengths in these disciplines to meet increasingly global regulatory requirements, including those relating to the European Biocidal Products Directive (“BPD”), which requires biocide manufacturers to re-register their biocidal products for sale in

the EU, and the EU’s Registration, Evaluation and Authorization of Chemical Substances (REACH) legislation. While some companies view these increasing foreign regulations as a hindrance or barrier, the Company sees it as a competitive advantage.”⁷⁴

Chemtura

Many companies that addressed the REACH initiative predicted negative impact. Chemtura, a producer of brominated flame retardants which are expected to be impacted by the REACH law, simply reports in its 2006 10-K, “The Company does not anticipate any impact to its financial position or results of operations in 2007; however, the impact of this legislation in 2008 and beyond is unknown at this time. It is possible that REACH may affect our ability to sell and manufacture some products.”⁷⁵

Behind the lines of this financial report—what the report fails to disclose—is that a significant portion of Chemtura’s business involves the sale of brominated flame retardants, which as a class of chemicals have become the focus of intensive scientific study and regulatory action for at least 10 years, as scientists have found various brominated flame retardants building up in the environment and have linked them to effects on the reproductive system, liver, and thyroid function of laboratory animals. Some of the most problematic brominated flame retardants are in the group of chemicals known as polybrominated diphenyl ethers (PBDEs). Two PBDEs, penta-BDE and octa-BDE forms, have been widely banned by regulators in Europe and the United States. The European Union’s ban took effect in 2004. Great Lakes Chemical Company, which in 2005 merged with Crompton Corporation to form Chemtura, voluntarily withdrew these chemicals from the US market, after California banned them in 2003. Nine additional states have since outlawed them.

Now another PBDE, deca-BDE, is coming under increased pressure in Europe and the US for prohibitions. The State of Washington enacted

a ban on deca-BDE in mattresses in 2007 and a ban in TVs, computers, and residential upholstered furniture effective in 2011 if safer, technically feasible substitutes are found. Maine has banned deca-BDE from mattresses and residential upholstered furniture beginning January 1, 2008, and bans televisions, computers or other electronic devices having deca- in their outside casing in 2010. Deca- bans have been introduced in other state legislatures. Dell and Hewlett-Packard are among the companies that have banned deca- from their products. Norway and the European Parliament have filed legal challenges to an exemption that currently allows continued use of deca-BDE in electronics products in the European Union.

Chemtura does not discuss and analyze these important trends that may materially affect the company.

Cytec Industries

In 2006, Cytec Industries reported, "we do not expect to incur significant costs for REACH compliance in 2007. However, the overall cost of compliance over the next 10-15 years could be substantial. In addition, it is possible that REACH may affect raw material supply, customer demand for certain products, and our decision to continue to manufacture and sell certain products."⁷⁶ In 2007, they added, "the registration, evaluation and authorization phases would require expenditures and resource commitments, for example, in order to compile and file comprehensive reports, including testing data, on each chemical substance and perform chemical safety assessments. We do not expect to incur significant costs for REACH compliance in 2008. However, the overall cost of compliance over the next 10-15 years could be substantial. In addition, it is possible that REACH may affect raw material supply, customer demand for certain products, and our decision to continue to manufacture and sell certain products in the European Union."⁷⁷ The fact that certain products may no longer be manufactured and/or sold in the European Union indicates

that this company predicts a negative impact from REACH.

Sealed Air Corporation

While some companies have increased their disclosure on the risks, liabilities, and opportunities surrounding REACH, others produced vague language and neglected to address the issue in subsequent annual reports. In its 2006 10-K, Sealed Air Corporation reports, "As a manufacturer, the Company is subject to various laws, rules and regulations in the countries, jurisdictions and localities in which it operates covering the release of materials into the environment, regarding standards for the treatment, storage and disposal of solid and hazardous wastes or otherwise relating to the protection of the environment. The Company is working with its suppliers to manage the impact of REACH on its operations and to insure compliance with its provisions. The Company reviews environmental laws and regulations pertaining to its operations and believes that compliance with current environmental laws and regulations has not had a material effect on the Company's capital expenditures or financial position."⁷⁸ The 2007 10-K fails to mention REACH at all.⁷⁹

Evaluating Disclosure by Companies Producing Articles or Preparations Imported to Europe (Chemical "Users")

Companies that import manufactured goods, or articles, to the European Union, as well as "chemical preparations" that are essentially mixtures of chemicals sold as products, are impacted by REACH. "The REACH Regulation defines an article as "...an object which during manufacture is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition." Most of the objects around the home will be considered articles, e.g., clothes, furniture, vehicles, toys and so on. Importers of "Articles" under the terms of the law only have to pre-register substance(s) with-

in an article if the substance is “intended to be released during normal or reasonably foreseeable conditions of use” and if the total amount of that substance exceeds one metric tonne per year per importer.⁸⁰

Two other duties are important for importers into the EU of articles. First, there is a duty to notify of any substances of very high concern (SVHC) in imported articles present above 0.1% and one metric tonne or more per importer per year. Second, recipients (downstream users, but not consumers) of articles must be provided with information on SVHCs (“sufficient information...to allow safe use”) present in articles above 0.1%. Consumers must be provided with this information “on request”. This second duty applies as soon as a substance is included on a list of SVHCs, with the first list likely to be published this year. Companies must therefore take immediate steps to understand exactly what substances are present in articles they export into the EU.

Now that REACH is going into effect, companies like RC2 and Mattel, that previously suffered massive recalls for lead paint on toys, may avoid these troubles because they need to systematically understand what substances are in articles exported into the EU.⁸¹

REACH’s requirements have a profound implication for US companies that do business in the EU. A company that produces or imports products into the EU has to know, and in some cases pre-register, the substances in those products. In the absence of pre-registration, notification, and information to customers, if required, products could be excluded from EU markets. Thus, for many US companies, REACH means that continuing to sell products to the EU necessitates much greater knowledge of the materials contained in the products, and a materials management system for tracking those contents.

For US consumer goods manufacturers exporting to Europe, REACH demands more knowledge of a product’s chemical contents. Yet strikingly few companies disclosed awareness or preparations under the law.

Given the enormous implications for producers of preparations and articles in the US for import to Europe, one would expect substantial work by producers to prepare for implementation of the law. However, our search for reporting by producers of articles and preparations showed remarkably little awareness or disclosure. We searched Edgar filings of companies within the last year within some industrial sectors that likely have large implications under REACH—SIC codes 2840 (soap, detergents, cleaning preparations, perfumes, and cosmetics) and 2851 (paints, varnishes, lacquers, enamels, and allied products). We searched the filings for discussion of REACH.

Despite the major implications, very few companies within these SIC codes addressed REACH at all in their 2007 Annual Reports. Within code 2851 (paints, varnishes, lacquers, enamels, and allied products), only Ferro Corp and PPG Industries mentioned REACH.

PPG Industries, with 24% of sales in Europe, notes, “PPG is currently reviewing the implementation guidance being developed by the European Chemicals Agency. Activities underway include establishing a dedicated organization within PPG to manage our implementation of REACH, reviewing our raw materials to identify substances potentially affected by REACH, working with our suppliers to understand the future availability and viability of the raw materials we use in our production process and creating a REACH steering committee consisting of high-level

stakeholders to guide, review and approve overall Company activities.”⁸²

The 2007 10-K also notes:

PPG anticipates that some current raw materials and products may be subject to the REACH authorization process and believes that PPG will be able to demonstrate adequate risk management for the use and application of the majority of such substances. PPG anticipates that compliance with the REACH legislation will increase costs due to registration costs, product testing and reformulation, risk characterization and report preparation; however, at this time it is not possible to quantify the financial impact on PPG’s businesses.⁸³

PriceWaterhouseCoopers reports that 55% of US companies say that they have little or no awareness of the requirements of REACH.

As with other companies, PPG Industries stops short of identifying what portion or examples of its product lines are already known to qualify for review under the authorization phase of REACH.

Ferro Corp noted that REACH could impact the company financially, but did not discuss any preparations for this regulatory change. Approximately 57% of Ferro Corp’s revenue is generated internationally.⁸⁴ The company states:

“Regulatory authorities in the U.S., European Union and elsewhere are taking a much more aggressive approach to regulating hazardous materials, and those regulations could affect sales of our products. Hazardous material legislation and regulations can restrict the sale of products and/or increase the cost of producing them. Some of our products are subject to restrictions under laws or regulations such as California Proposition 65 or the

European Union’s (“EU”) hazardous substances directive. The EU “REACH” registration system became effective June 1, 2007, and requires us to perform toxicity studies of the components of some of our products and to register the information in a central database, increasing the cost of these products. As a result of these hazardous material regulations, customers may avoid purchasing some products in favor of perceived “greener,” less hazardous or less costly alternatives. This factor could adversely affect our sales and operating profits.”⁸⁵

Searching SIC code 2840 (soap, detergents, cleaning preparations, perfumes, and cosmetics) found only three companies that discuss REACH in their annual reports. Ecolab discloses very little, saying “to manage this new program, we are simplifying our product line and working with chemical suppliers to comply with registration requirements. The eventual impact of REACH will also be felt by our competitors. Potential costs to us are not yet fully quantifiable, but are not expected to significantly affect our consolidated results of operations, financial position or cash flows.”⁸⁶

The above were the best disclosures in these sectors; a vast number of other companies doing business in Europe from these sectors failed to report anything about the implications of REACH on their businesses. Procter & Gamble is an example of a company with a large portion of sales in Europe (sales in Western Europe accounted for 23% of all sales.)⁸⁷ Yet the company did not even discuss REACH in its most recent 10K.

To cite another example, Mattel is obviously aware of the financial impact of bringing hazardous products to market because of the recent lead paint recalls. In its most recent 10-K, Mattel describes its international segment, “Products marketed by the International segment are generally the same as those developed and marketed by the Domestic segment, with the

exception of American Girl Brands, although some are developed or adapted for particular international markets. Mattel's products are sold directly to retailers and wholesalers in most European, Latin American, and Asian countries, and in Australia, Canada, and New Zealand, and through agents and distributors in those countries where Mattel has no direct presence."⁸⁸ Mattel's International segment revenue represented 49% of its worldwide consolidated gross sales in 2007. Sales in Europe accounted for 56% of all of all International gross sales.⁸⁹ Although Europe is a major market for this company, Mattel neglects to describe how it will be affected by REACH.

Consistent with the lack of disclosure by US companies, a survey of companies conducted by PriceWaterhouseCoopers (PWC) found that 55% of US companies say that they have little or no awareness of the requirements of REACH. Most companies had not discussed the law with customers and suppliers to determine the impact on their supply chains. PWC concluded

that US companies will "suffer significant business disruptions" as a result of their lack of preparedness. But no companies that we found are disclosing these significant business disruptions, even though this may include exclusion of noncomplying products from EU markets.⁹⁰

The lack of disclosure by major US importers of articles and preparations to Europe appears to confirm that many companies are ill-prepared for the preregistration requirements that require compliance later this year. It also means that investors are ill-informed about the level of preparation of these companies, and the degree to which they may be impacted.

Despite the major financial implications, very few companies that export articles to Europe discuss REACH at all in their 2007 Annual Reports.

Anticipating Impacts of Emerging Science Findings About Product Hazards

Many a public health issue begins as a debate in the scientific literature. While today their health hazards are largely beyond debate, the health impacts of asbestos and tobacco were first flagged by a growing number of scientific studies. At what point in the process should the companies have disclosed these studies that indicated serious hazards of their products, and foreshadowed massive corporate liabilities? By and large, the current practice in corporate reporting is for management discussion and analysis to ignore adverse scientific studies, or to adopt a defensive stance. There is seldom a neutral and straightforward discussion of the science that acknowledges red flags about product safety, even though the company may also hire scientists to mount a defense of the safety of materials.

Although the issues raised in early scientific findings start off below the radar of regulatory officials, discussion of potential hazards identified in the scientific literature could, if made accessible to investors, provide early warnings of eventual, serious financial implications.

Below we evaluate three examples of emerging science that have, or may have, serious financial implications for companies and their investors: nanomaterials, evidence linking pesticides and other chemicals to asthma, and PFOA (perfluorooctanoic acid).

Nanomaterials

Nanotech Risks are Poorly Evaluated and Minimally Regulated

Nanotechnology is a rapidly growing force in the marketplace, with sales of products incor-

porating nanotechnology doubling from 2004 to 2005 to reach \$32 billion. Nanomaterials are particles smaller than 1,000 nanometers (nm). For a sense of scale, a human hair measures 100,000 nm across. Current annual worldwide investment in nanotechnology research is over \$9.6 billion, and more than 2 million people work in the development, production, or use of nanomaterials. The nanotech field is so young that it was not subject to any special legislation, regulations, or recommendations on handling or labeling until early 2004. However, both the scientific community and risk assessors have already raised serious questions about the safety of nanomaterials.

Early scientific findings of product hazards emerge long before regulation takes hold. More balanced corporate disclosure of those finds would provide early warnings to investors of potential marketplace shifts, as well as longer term liability and regulatory risks.

Nanotechnology as an emerging field raises important questions about regulation and the potential hazards of exposure. One group that addresses this interface between science and policy is The Project on Emerging Nanotechnologies, which was established in April 2005 as a partnership between the Woodrow Wilson International Center for Scholars and the Pew Charitable Trusts. The Project is "dedicated to helping ensure that as nanotechnologies

advance, possible risks are minimized, public and consumer engagement remains strong, and the potential benefits of these new technologies are realized." They collaborate with researchers, government, industry, policymakers, and others to identify gaps in knowledge and regulatory processes, and to develop strategies for closing them.⁹¹

Because this subject is important to risk assessors, the insurance company Swiss Re has "launched numerous initiatives to raise awareness of this emerging technology, the risks and opportunities associated with it and its possible implications for the insurance industry."⁹² Their recent report, "Nanotechnology: Small Matter, Many Unknowns," discusses this emerging technology and its associated risks and opportunities. The following summary relies heavily on these two sources.

Nanomaterials can represent a threat to health and safety because, as particle size decreases and reactivity increases, harmful effects can be intensified, and normally harmless substances can take on hazardous characteristics.⁹³ Laboratory studies indicate that nanomaterials pose a unique set of risk factors. Some nanoparticles ingested from food or water, or breathed in, can pass through the intestinal walls or lungs and reach the bloodstream, allowing them almost unrestricted access to the human body. Once in the blood, their size allows some nanomaterials to access to the brain, as they can pass the blood-brain barrier.⁹⁴ Nanoparticles can interrupt important chemical communication between enzymes and hormones, and can cause immune responses.⁹⁵ Many types of nanoparticles interfere with normal cellular function, causing oxidative damage and cell death.

Scientists currently do not clearly understand how nanoparticles are absorbed, how they move around in the body and bloodstream, or how they are excreted. However, current research shows that many these particles are biologically relevant simply because of their size and

Carbon nanotubes are similar in shape and rigidity to asbestos fibers. Already widely used in products, there is reason to believe their health impacts may be similar to asbestos as well.

unprecedented access to the body. Carbon nanotubes, for example, are similar in shape and rigidity to asbestos fibers. Like nanoparticles, asbestos showed great promise from the outset, and was used widely because of its durability and fire-resistance. Asbestos fibers were not technically toxic or chemically suspect, yet they cause serious damage to lung tissue merely on account of their form and size, consequences that were only discovered years later.

In a report on the impact of nanotechnology, Innovest Strategic Value Advisors highlights this issue. "Numerous reports attempt to characterize the environmental, health and safety risks associated with specific types of particles. This is interesting considering the limited amount of research and scientific review that has been published. Investors may note that many chemical structures have been approved by regulators and characterized as being safe. Only later do their toxic properties come to light resulting in significant liability."⁹⁶

Despite early warnings about the effects of asbestos on health, it took 100 years to introduce internationally accepted asbestos standards. The chronic danger of exposure to nanoparticles could similarly take time before it manifests itself. Multiple laboratories have already independently reported that carbon nanotubes cause progressive, irreversible lung damage in test rodents.⁹⁷ As noted above, this may be because carbon nanotubes are similar in form and size to asbestos fibers. Product liability may also arise from other similarities between nanotechnology and asbestos, such as their worldwide

dissemination and wide range of uses. Carbon nanotubes already have a variety of uses, from tennis rackets and bicycles, to displays and TV screens, and a variety of resins used by aerospace, defense, health care, and electronics companies.⁹⁸

A variety of nanomaterials possess novel qualities (shape, size, chemical reactivity) creating the potential to make them especially dangerous. Some nanoparticles are given special characteristics during the manufacturing process. Coating prevents nanoparticles from clumping together, and these coated nanoparticles are extremely mobile in the environment. Traditional water filtration systems do not capture them, and once in the air they do not settle like heavier particles. They may only stop moving when they are inhaled or otherwise limited. The smallest nanoparticles easily move through various strata of the earth.⁹⁹

Despite the potential dangers, sunscreen and cosmetics—personal care products likely to be applied directly to the body by biologically sensitive groups such as children and pregnant or nursing women—currently contain nanoparticles, along with a variety of electronics and other consumer goods.

In the absence of long-term toxicological studies, it is difficult to determine the degree of risk posed by the presence of nanoparticles in the body or environment. However, risk assessors are focusing on these questions, and recognize the extreme complexity of the problem. According to the Swiss Re report:

Nanotechnology may well belong to the category of revolutionary risks that can be shown to have harmful consequences.... At the same time, the assessment of potential losses must be assumed to be either impossible or at least very difficult with regard to their scale, location and time of occurrence. What makes nanotechnology completely new from the point of view of insuring against

risk is the unforeseeable nature of the risks it entails and the recurrent and cumulative losses it could lead to, given the new properties—hence different behavior—of nanotechnologically manufactured products.¹⁰⁰

[I]f systemic defects only emerge over time... unforeseeably large loss potential could accumulate, for example, in the field of health impairment.

—Swiss Re Nanotech Report

A discussion of market risk and liability of nanomaterials is imperative for any company involved in this rapidly growing field. According to the Swiss Re report, an inattention to nano-specific risk research puts more than consumers and the environment in danger. It sets up a scenario in which the future promise of nanotechnology in such fields as robotics, medical technology, and computer science could suffer serious setbacks, when predictable and preventable problems emerge as “market-jarring surprises.” It is very likely that a cause and effect relationship will be established between nanoparticles and human health effects, because these particles have historically unprecedented access to the human body. Swiss Re also points out that “these artificially manufactured nanoparticles will be traceable back to the manufacturer, which makes the establishment of liability easier than in the case of substances that are universally present, such as ultrafine particles from diesel exhaust fumes.”¹⁰¹

Professional risk assessors already recognize the inherent danger in fast-emerging technologies where risks and liabilities are not immediately apparent. According to risk assessors at Swiss Re, “Risks arising out of the introduction of new products or innovative technologies need not reveal themselves immediately and may occur after an interval of years. Nanotechnology is set

to spread to such a wide range of industries and in such a large number of applications and at such speed, that the individual claims conceivable on the basis of experience and resulting from defects can hardly expect to be long delayed. Things will become critical if systemic defects only emerge over time, or if a systematic change in behavior remains undetected for a long time. In that case, an unforeseeably large loss potential could accumulate, for example, in the field of health impairment."¹⁰²

Limited disclosure of risks associated with nanotechnology

Companies currently exhibit a range of disclosure practices regarding the risks of nanotechnology. While some discuss health risk implications, others gloss over these complicated liabilities. In general we observed that some of the specialists in the manufacture of nanotech products tended to engage in broader disclosure of potential health risks than those using nanotech as part of established consumer product lines.

Nanomanufacturing sectors

For example, Arrowhead Research Corporation is commercializing a variety of nanotech products and applications, including anti-cancer drugs, RNAi therapeutics, fullerene-based antioxidants, carbon-based electronics and compound semiconductor materials. In its January 22, 2008 SB-2 form, the company discloses, "Nanotechnology-enabled products, such as those used in our chemical detection technologies, are new and may be viewed as being harmful to human health or the environment."¹⁰³ They also include a discussion of health risk concerns surrounding nanotechnology, and how these could affect market value. "There is increasing public concern about the environmental and ethical implications of nanotechnology that could impede or delay market acceptance of products developed through these means. Nanotechnology-enabled products are mainly composed of materials such as carbon, silicon, silicon carbide, germanium, gallium

arsenide, gallium nitride, cadmium selenide or indium phosphide. Because of the size, shape or composition of the nanostructures or because they may contain harmful elements, nanotechnology-enabled products could pose a safety risk to human health or the environment. The regulation and limitation of the kinds of materials used in or to develop nanotechnology-enabled products, or the regulation of the products themselves, could harm the commercialization of nanotechnology-enabled products and impair our ability to achieve revenue from the license of nanotechnology applications."¹⁰⁴

Luna Innovations Incorporated acknowledges the limited safety record of nanomaterials, and foresees federal regulations surrounding nanotechnology. This company is involved in development and commercialization of technologies in two primary areas of focus: instrumentation products and healthcare products. In an August 2007 quarterly report, they state:

Our nanotechnology-enabled products are new and may be, or may be perceived as being, harmful to human health or the environment. While none of our current products are known by us to be hazardous or subject to environmental regulation, it is possible our current or future products, particularly carbon-based nanomaterials, may become subject to environmental regulation. We intend to develop and sell carbon-based nanomaterials as well as nanotechnology-enabled products, which are products that include nanomaterials as a component to enhance those products' performance. Nanomaterials and nanotechnology-enabled products have a limited historical safety record. Because of their size or shape or because they may contain harmful elements, such as gadolinium and other rare-earth metals, our products could pose a safety risk to human health or the environment. These characteristics may also cause countries to adopt regulations in the future prohibiting

or limiting the manufacture, distribution or use of nanomaterials or nanotechnology-enabled products. Such regulations may inhibit our ability to sell some products containing those materials and thereby harm our business or impair our ability to develop commercially viable products. The subject of nanotechnology has received negative publicity and has aroused public debate. Government authorities could, for social or other purposes, prohibit or regulate the use of nanotechnology. Ethical and other concerns about nanotechnology could adversely affect acceptance of our potential products or lead to government regulation of nanotechnology-enabled products.¹⁰⁵

Nano-Proprietary Inc., a company that focuses on applications of carbon nanotube technology, makes a similar prediction of future regulations on nanotechnology in its 2007 10-K:

Products using our technology will be subject to extensive government regulation in the United States and in other countries. In order to produce and market existing and proposed products using our technology, our licensees must satisfy mandatory safety standards established by the U.S. Occupational Safety and Health Administration ("OSHA"), pollution control standards established by the U.S. Environmental Protection Agency ("EPA") and comparable state and foreign regulatory agencies. We may also be subject to regulation under the Radiation Control for Health and Safety Act administered by the Center for Devices and Radiological Health ("CDRH") of the U.S. Food and Drug Administration. We do not believe that carbon nanotube field emission products will present any significant occupational risks to the operators of such equipment. In addition, the carbon nanotube field emission products are not expected to produce significant hazardous or toxic waste that would require extraordinary disposal procedures. Nevertheless, OSHA, the EPA, the CDRH and other

governmental agencies, both in the United States and in foreign countries, may adopt additional rules and regulations that may affect us and products using our technology.¹⁰⁶

Nanoproprietary Inc. also notes:

The health effects of nanotechnology are unknown

There is no scientific agreement on the health effects of nanomaterials, but some scientists believe that in some cases, nanomaterials may be hazardous to an individual's health or the environment. The science of nanotechnology is based on arranging atoms in such a way as to modify or build materials not made in nature; therefore the effects are unknown. The Company takes appropriate precautions for its employees working with carbon nanotubes and believes that any health risks related to carbon nanotubes used in potential products can be minimized. Future research into the effects of nanomaterials in general, and carbon nanotubes in particular, on health and environmental issues may have an adverse effect on products using our technology.

It is an example of a helpful disclosure development that some manufacturers of nanotube products are making specific reference to the health concerns about nanotubes materials in particular. For instance, CVD Equipment Corp, goes the furthest of any company in acknowledging the concerns about its nanotubes products:

The health and environmental effects of nanotechnology are unknown, and this uncertainty could adversely affect the expansion of our business.

The health effects of nanotechnology are unknown. There is no scientific agreement on the health effects of nanomaterials in general and carbon nanotubes, in particular, but

some scientists believe that in some cases, nanomaterials may be hazardous to an individual's health or to the environment. The science of nanotechnology is based on arranging atoms in such a way as to modify or build materials not made in nature; therefore, the effects are unknown. Future research into the effects of nanomaterials in general, and carbon nanotubes in particular, on health and environmental issues, may have an adverse effect on products incorporating nanotechnology. Since part of our growth strategy is based on sales of research equipment for the production of carbon nanotubes and the sale of such materials, the determination that these materials are harmful could adversely affect the expansion of our business.¹⁰⁷

By contrast, NaturalNano Inc. talks at length about its use of nanotubes technologies in health and beauty products and clothing, without flagging the health risk concerns relative to nanotubes.¹⁰⁸

Although nanotubes are an example of a nanotechnology that may have some of the most serious risks given their structural similarities to asbestos, and manufacturers are making some vague references to potential health concerns and regulatory risks, our review of SEC filings showed that the users who add these substances to their products are making few if any disclosures of the uses, the potential health risks based on their structures, and the financial risks to user companies.

Users of nanoparticles of titanium dioxide

In contrast to the nanotech-focused manufacturers, companies using nanomaterials in their consumer products tend to acknowledge the opportunities that innovations such as nanotechnology offer, yet do not address the associated risks. In its 2007 10-K filing, Procter & Gamble focuses on emerging technologies and innovation as a strength in the company, but does not specifically mention nanotechnology or its associated potential risks or liabilities.¹⁰⁹

The company's website includes a discussion of nanotechnology in its research and development section.¹¹⁰ The summary on the website focuses on the documented safety of ultrafine metal oxides used in sunscreens, implying that nanoscale products should be equally safe, although ultrafine particles are generally much larger than nanoscale particles.

The company concludes, "With a long history of safe use in FDA-regulated products and a demonstrated lack of dermal absorption, there is extensive confirmatory evidence that nanoscale zinc oxide and titanium dioxide may be safely used in cosmetics and OTC drug products."¹¹¹

At least one company talks at length about its use of nanotube technologies in health and beauty products and clothing, without flagging health risk concerns regarding nanotubes.

The cosmetics company Avon has made similar claims of product safety. In its spring 2008 statement in opposition to a shareholder resolution requesting a report on Avon's policies on nanomaterials product safety, the company broadly asserts in the proxy that these materials are safe. "Avon's evaluation included a specific assessment of the potential for nano-sized particles of these materials to be absorbed through the skin (several scientific studies have demonstrated that nano-sized titanium dioxide and zinc oxide do *not* penetrate the skin). In the opinion of Avon's scientists (toxicologists and other safety professionals) each of these materials can be used safely in cosmetic products."¹¹²

Neither Avon nor Procter & Gamble gives a balanced presentation of the scientific concerns about nanoparticles. Some recent research on sunscreen ingredients in humans supports

For nanoparticle-based sunscreens, no publicly available information exists on whether penetration could occur through skin that is injured, sunburnt, or abraded.

Avon's and Procter & Gamble's safety claim that the nanoparticles in sunscreen do not penetrate the skin,^{113,114} but others question whether testing is thorough enough to determine safety. No publicly available information exists on whether penetration could occur through skin that is injured, sunburnt, or abraded.

Additionally, many nanoparticles are coated or contain other materials; these variables could affect toxicity and penetration. Exposure to UV radiation, which would logically happen to nanoparticles in sunscreens, might change the reactivity of nanoparticles.

The uncertainties concerning safety of the nanoparticles used in sunscreens is questioned by Wall Street advisory firm Innovest Strategic Value Advisors, which recently identified nanoparticle safety for Titanium Dioxide as a financial risk.¹¹⁵ They noted:

While titanium dioxide (TiO₂) has been approved by the Scientific Committee on Cosmetics and Non-food Products (SCCNFP) in Europe and given a green light by the Food and Drug Administration in the United States, we are cautious about these findings for the following reasons:

- In February 2006 titanium dioxide was classified by the International Agency for Research on Cancer (IARC) as an IARC Group 2B carcinogen "possibly carcinogen to humans". The evidence showed that

high concentrations of pigment-grade (powdered) and ultrafine titanium dioxide dust caused respiratory tract cancer in rats exposed by inhalation and intratracheal instillation.

- A 1997 study suggests that TiO₂ may cause DNA damage, and the science is still uncertain regarding possible effects on damaged skin.
- The Scientific Committee on Cosmetics and Non-food Products (SCCNFP) used proprietary company studies to determine safety rather than setting preference for independent toxicity testing. Investors may note that the chemicals industry's credibility problem could be partly attributable to this and may explain the existence of programs like the OECD's High Product Volume Challenge, which takes proprietary company data and makes it public for peer review.

In 2007 Europe's Scientific Committee on Consumer Products raised additional questions on the safety of nanomaterials in sunscreens. They stated in their Preliminary Opinion on Safety of Nanomaterials in Cosmetics Products, "For the nanomaterials used in sunscreen products, a safety dossier on nanosized Zinc Oxide (ZnO) was requested by SCCNFP in its opinion on ZnO in 2003 (SCCNFP/0649/03). An opinion on the safety of such material will be dependent on an adequate dossier. Since the SCCNFO opinion on titanium dioxide (TiO₂) (SCCNFP/0005/98), much new scientific data on nanosized particles, including TiO₂, have emerged. Therefore, the SCCP considers it necessary to review the safety of nanosized TiO₂ in the light of recent information and to consider the influence of physiologically abnormal skin and the possible impact of mechanical action on skin penetration."¹¹⁶

Users of the sunscreen nanoparticles such as Avon and Procter & Gamble may be prematurely asserting safety, and neglecting to present a balanced picture of the limitations of testing conducted to date. Untested variables could influence the ability for nanoparticles to penetrate the skin or otherwise enter the body, including incidental consumption of the particles applied to the face, via the mouth. Investors should be apprised of the state of the science by a company, instead of being misled to believe that the serious questions have been answered.

Products that may cause or exacerbate asthma

According to the Centers for Disease Control and Prevention (CDC),¹¹⁷ asthma rates are on the rise in the US, growing 74 percent from 1980 to 1996 and reaching epidemic proportions now with 16 million people afflicted with the disease. Asthma ranks within the top ten conditions causing limitation of activity,¹¹⁸ and asthma-related health care, loss of work productivity, and premature deaths cost \$16.1 billion annually in the US.¹¹⁹

Studies have shown that adults who did not previously suffer from this chronic condition can develop asthma after exposure to certain chemicals.^{120,121} Occupational asthma, which accounts for approximately 15% of adult asthma, affects the health of many US workers.¹²²

Pesticides

Several studies¹²³ have found that exposure to chemicals early in life may contribute to the development of asthma. According to a 2004 study in *Environmental Health Perspectives*, pesticides are both a trigger and root cause of asthma. Researchers discovered that children exposed to herbicides are four-and-a-half times more likely to be diagnosed with asthma before age five; toddlers exposed to insecticides are over two times more likely to get asthma.¹²⁴ Another recent study found that infants ex-

posed to herbicides and pesticides before age one were more likely to develop asthma.¹²⁵ The estimated annual cost of treating childhood asthma is \$3.2 billion.¹²⁶

Chemical companies large and small may see their liability increase as evidence accumulates connecting chemical exposure with asthma. For instance, approximately half of Dow Chemical's end-use pesticide products (73 of 149) may be linked to asthma and other respiratory problems through active or inert ingredients or

Researchers found children exposed to herbicides four-and-a-half times more likely to have asthma before age five; toddlers exposed to insecticides were twice as likely.

metabolites. Common Dow pesticide products with ingredients linked to respiratory problems include: FulTime, Dursban, Glyphomax, Tordon, Telone, Starane, Dithane, Widematch and more. In addition to its retail and wholesale pesticide products, Dow produces many active ingredients in pesticides ultimately sold by other companies. For example, Dow is the sole US producer of 2,4-D, and one of the world's largest producers of chlorpyrifos. There is evidence to suggest that these chemicals cause or exacerbate asthma.¹²⁷ Exposure to these chemicals is widespread. Data from CDC's 2005 *National Report on Human Exposure to Environmental Chemicals* show that more than three-quarters (76 percent) of Americans have chlorpyrifos metabolites in their bodies, with concentrations in children aged six to 11 at four times the level EPA considers acceptable for long-term exposure.¹²⁸ Additionally, more than a quarter of Americans have 2,4-D in their bodies, with highest concentrations also found in children ages six to 11.¹²⁹ Such biomonitoring data may aid in the correlation of chemical exposures with asthma and

The connection between exposure to product chemicals and asthma is receiving no coverage in companies' financial reports.

other diseases, which could in turn increase legal liabilities for Dow and other companies.

Cleaning Products

Cleaning products promise to protect a family's health by killing germs, yet many contain chemicals that may actually be harmful to health, with effects that can include causing or exacerbating asthma. In July 2007, the nonprofit organization Women's Voices for the Earth published a report entitled "Household Hazards: Potential Hazards of Home Cleaning Products." This report provided information on the toxic effects of exposure to certain chemicals.¹³⁰

For example, the report highlighted Monoethanolamine (MEA), a surfactant found in some liquid laundry detergents, all-purpose cleaners, and floor cleaners. This chemical is a known inducer of occupational asthma in cleaning workers.^{131,132} Although research has not been conducted specifically to assess the impacts on residential uses of products containing MEA, the scientific community has identified good reason to be concerned about asthma-triggering exposures of vulnerable populations in the home. Small children, for example, have increased sensitivity to asthma-inducing substances because their lungs are still developing; people with existing lung conditions could have a compromised ability to handle additional lung stress from exposure to inducers. Yet these populations are exposed to this chemical in household settings when they use cleaning products. For instance, according to the MSDS (Material Safety Data Sheets) available on Procter & Gamble's website in May 2007, Procter & Gamble manufactures 29 individual products that contain MEA. These products include Tide, Ace, Ariel, Liquid ERA and Cheer laundry detergents,

containing 0.5-1.5% MEA, Gain laundry detergents containing 1-5% MEA, and Dawn Power Dissolver Kitchen cleaner, which contains 3-7% MEA.

Disclosure of potential for products to contribute to asthma

Thus far, the connection between chemical exposure and asthma is receiving no coverage in companies' financial reports. The only coverage of this issue we found in SEC filings¹³³ was in the Dow Chemical proxy as a result of a shareholder resolution by Trillium Asset Management asking the company to report on the extent to which its product lines may cause or exacerbate asthma, and the company's policy responses.¹³⁴ In its opposition statement to the resolution, the company takes the position of minimizing the strength and significance of the emerging science. While acknowledging that some peer reviewed articles have found that there is an association between pesticides and respiratory conditions, the company states that there is no scientific or regulatory consensus that pesticides are a significant cause or trigger of asthma. It suggests that this is a more appropriate issue for regulators to study than the company. It is apparent from the other examples in this report that such an outlook—resting on a company's own defensive scientific posture and awaiting regulatory restrictions rather than examining and acting to curtail health effects—may well expose the company to serious financial and marketplace ramifications as regulators, consumers, and litigators catch up with the findings of the scientific community. As with the other issues, it may be only matter of time until this issue brings financial repercussions for companies such as Dow Chemical, Procter & Gamble, and their shareholders.

DuPont and PFOA

PFOA (perfluorooctanoic acid) is a chemical used as a processing aid in the manufacture of fluoroelastomers (synthetic, rubber-like materials used in gaskets, O-rings and hoses) and fluo-

ropolymers (low-friction substances with high resistance to solvents, acids, and bases used in cookware and apparel as well as computer chip processing equipment and systems and other applications). PFOA is currently manufactured in the US only by DuPont. The history of PFOA shows how DuPont has aggressively sought to minimize its recognition of emerging science demonstrating potential health and financial risks of staying the course with this product, and yet has eventually had to succumb to market, regulatory and competitive pressures to migrate out of these materials.

PFOA's status as a problem chemical begins with the facts that it does not break down in the environment and is believed to be present in the blood of more than 90 percent of Americans.¹³⁵ PFOA has been detected in household dust in consumers' homes in several states, and in surface, ground or drinking near DuPont facilities in Parkersburg, WV, Richmond, VA, Fayetteville, NC and Circleville, OH.

While the company has consistently taken the position that PFOA does not harm human health, a growing volume of scientific studies have mounted to contradict that position. Studies have suggested a potential role of PFOA in birth defects and irregularities, various cancers, strokes, and other concerns. Recent preliminary studies by Johns Hopkins University indicate that PFOA is likely to impair the normal growth of a developing fetus.

Despite the company's continuing denial of health effects, under pressure from regulators, NGOs, investors and customers, DuPont recently announced its intention to phase out the production and use of PFOA by 2015.

DuPont disclosures deferred

DuPont has long asserted in its financial reports that it believes PFOA does not harm human health. Its financial reports chronicled the company's growing enforcement and litigation challenges on this chemical, but not of the mounting

science against the chemical, or of the array of DuPont manufacturing sites being discovered to be contaminated with PFOA.

Beginning in 2005 a group of DuPont shareholders¹³⁶ filed a report and series of letters with the SEC requesting an investigation of DuPont

Despite its continuing denial of health effects of PFOA, market and regulatory pressure has forced DuPont to phase out the production and use of PFOA. It has set a goal of 2015, though rapid shifts in consumer and manufacturer demand may cost the company part of its customer base long before then.

management's failure to disclose material information to investors regarding PFOA. The correspondence with the SEC requested an evaluation of whether the company should be required to disclose to investors:

- A more balanced description of the scientific evidence arrayed against PFOA, which suggests that it is likely to be harmful to human health despite the company's reiterated denials of such effects;
- Liability indicators such as environmental contamination and blood tests associated with all DuPont facilities where PFOA is used or produced;
- Regulatory and market trends, including regulatory developments in Canada, Europe and Australia, and consumer and retail developments that may restrict markets for DuPont products.

Subsequent to these shareholder letters, staff at the SEC sent to DuPont a series of inquiries on how it discloses liabilities, expenses and science regarding PFOA. The correspondence resulted in disclosure to the SEC of \$11 million in legal fees, research and communications costs associated with PFOA during 2005. The company also acknowledged that it viewed it as “reasonably possible” that DuPont could incur additional liabilities at other facilities relative to PFOA releases, but said that it was unable to quantify such liabilities.

After the initial responses and issuance of the 2005 10-K (issued February 2006) the SEC wrote again to the company April 21, 2006, with specific instructions and remarks regarding the company’s duty to disclose in future reports :

In your most recent response you state that it is reasonably possible that you will incur losses related to exposure to PFOA from sources other than Washington Works [the West Virginia plant subject to the most scrutiny], but because you are not aware of any particular source that may cause such loss, a range of loss, if any, cannot be reasonably estimated at this time. However, because losses are reasonably possible we urge you to carefully consider the following areas when you determine the probability of loss, estimates of amounts, and other disclosures related to risks and uncertainties. In future filings, where appropriate, should address the following in better detail:

- current and probable findings from the EPA, the Science Advisory Board, the independent science panel and their evaluation in West Virginia;
- current and probable findings by any other government, agency, or scientific study, either foreign or domestic;
- provide more detail concerning any findings you become aware of concerning the possible health impact of PFOA;

- emerging trends, by both institutions and consumers, concerning the safety of PFOA and any related products; and
- the amounts and underlying assumptions of any accruals and reasonably possible ranges of loss.¹³⁷

It should be noted that the subsequent DuPont 10-K reports for 2006 and 2007, issued after the SEC’s correspondence providing guidance for future disclosure, still failed to disclose many of the key developments implied by the SEC letter.

The company continued to assert its “belief” that PFOA does not harm human health, despite objections by its own epidemiology review board that its own studies did not support this assertion. A memo by the review board was published by the Charleston, WV Gazette, showing that the company’s own epidemiology review board disagreed with the company’s characterization of the science as not showing human health impacts, since the existing data did show that exposure was correlated with increased cholesterol—a risk factor for heart attack and stroke. Moreover, in March 2008, 3M revealed a new evaluation of prior statistics finding that the risk of workers’ death from prostate cancer and stroke was higher with higher estimated exposures to PFOA.¹³⁸

The company also still declined to disclose in its MD&A the highly notable preliminary findings of Johns Hopkins University regarding potential developmental toxicity impacts on humans. In early 2007 Johns Hopkins University researchers revealed a study which found that newborn human babies that had been exposed to low levels of PFOA had decreased birth weight and head circumference.¹³⁹ While the research is considered preliminary, it could represent a dramatic new piece of evidence of developmental effects in humans. Since that report was initially issued it has been backed up by an animal study finding that neonatal exposure to perfluorooctane sulfonate (PFOS) and perfluoro-

octanoic acid (PFOA) causes neurobehavioural defects in adult mice.¹⁴⁰

Despite years of arguing that PFOA causes no harm to health, the precautionary impulses of consumers, manufacturers, and regulators to avoid human exposures to PFOA eventually caught up with DuPont. While it was not disclosed in DuPont's filings, major retailers including McDonald's, H&M, and Wal-Mart announced their intent to use alternatives to PFOA-based products. ConAgra announced that it was studying replacements for PFOA-based food packaging. DuPont competitors moved quickly to find nonPFOA alternatives. For instance, Air Products, a DuPont competitor, has begun promoting non-PFOA emulsions and surfactants as alternatives to DuPont's fluorochemicals. 3M—the original supplier of PFOA—stopped producing PFOA due to environmental concerns. In 2006, it announced the relaunch of Scotchgard stain repellants, no longer based on perfluorinated compound chemistry.

In 2007 DuPont finally announced that it would exit production and use of PFOA, following up on an earlier declaration that it would seek to minimize the use of PFOA in products:

"DuPont is committed to no longer make, use or buy PFOA by 2015 or earlier, if possible. We are taking this action because studies have shown very low levels of this compound in the environment and in the blood of the general population. Questions about this, as well as customer interest in product alternatives, are leading DuPont to develop new products and processes that reduce our environmental footprint and are more environmentally sustainable."¹⁴¹

DuPont has never disaggregated the impact on shareholder value or company earnings such as the loss of customers or damage to reputation caused by the PFOA issues facing a broad swath of DuPont products.

It should be noted here in closing that the DuPont decision to eliminate the use and production of PFOA does not include a commitment to eliminate the use of other products that may break down to PFOA, such as fluorotelomers, which are a major product line for the company.¹⁴² The company currently asserts based on limited testing that it believes with its new formulations those products will not break down to PFOA.¹⁴³

DuPont has never disaggregated the impact on shareholder value or company earnings resulting from concerns related to PFOA, such as the loss of customers or damage to reputation caused by this dramatic product safety issue that relates to a broad swath of DuPont products. The only financial estimate of overall magnitude the company provided in its annual disclosures was to say that if PFOA were banned it could cost the company approximately \$1 billion per year.¹⁴⁴

Conclusions and Recommendations

Our analysis of corporate reporting on recalls and emerging scientific concerns indicates that companies are either not making pertinent disclosures at all or are relying on vague boilerplate comments; consequently, they are failing to inform investors of the actual state of a company's preparedness on risks to finances.

As demonstrated by the lead toy product recalls, public records or databases of government agencies may contain relevant trend information that should be known to companies. Since it is reasonable to expect affected companies in sectors such as toys to monitor those records, the companies should also be expected to discuss and analyze recall trends that are relevant to them, and disclose the extent to which they are reliant for products or materials from high risk regions such as China. This form of reporting was lacking from the toy company disclosures made prior to the toy recalls that we analyzed.

In regard to the European REACH program, disclosure by chemical companies is uneven, with some companies acknowledging REACH's potential to impact their operations while others address it in indocumented and largely dismissive terms; however, in general the companies are not providing available information to shareholders on the portion of their materials that may be subject to authorization and therefore may be excluded from EU markets. Disclosure on REACH is uneven across reporting chemical companies while being almost non-existent for chemical user companies doing business in Europe.

Some companies report that they anticipate no material impacts of REACH by relying heavily on assumptions about their ability to meet as yet

untested exemptions based on proving safe use of each of their products. In our opinion, such an assumption is likely an overreach, and results in poor transparency of issues with potentially material impacts on companies. As noted above, even if a company has not conducted testing on each of its chemicals, existing lists combined with the EPA's "PBT Profiler" provide a baseline of information sufficient to inform investors whether products are likely to be targeted by REACH for authorization.

The absence of clear SEC obligations to disclose scientific findings indicative of potential hazards of a company's products or activities is a major impediment to effective disclosure. It is common practice to use the existence of a company's defensive science (the "no harm" scientific findings of experts funded by the company) as a basis for either omitting discussion of adverse science, or of dismissing adverse science with a simplistic discussion of a company's viewpoint (e.g. We believe chemical X will not harm human health). This status quo is encouraged by current disclosure rules which allow a company's defensive science to color their judgment as to whether liabilities attendant to a chemical risk are "reasonably likely to be a material issue." Yet in the history of public health issues such as asbestos and tobacco, each company's defensive science only staved off the eventual liability for a limited period of time; in both cases, investors were not given fair warning in company disclosure documents.

To effectively do their job as fiduciaries, investment managers need to be able to benchmark chemical companies and chemical user companies on their management of these product toxicity issues. The current state of disclosure defies such benchmarking.

1. Chemical user and producer companies must do a better job of disclosure.

Financial report statements made prior to recalls regarding supply chain compliance safeguards may have seemed adequate at the time. But in hindsight, vague remarks on how materials are sourced and how compliance is ensured may have foreshadowed weaknesses in the supply chains that led to the recalls. Shareholders would benefit from clearer and more consistent disclosure.

Greater consistency is needed to describe where products and materials are sourced, and details should be sufficient to allow an informed investor to ponder whether a company's control systems are adequate to maximize compliance and product safety throughout supply chains that may be several tiers deep.

Some companies have showed the way to greater supply chain transparency on other issues outside of the product toxicity arena. For example, Gap Inc. set a high water mark in transparency in its 2003 *Social Responsibility Report* by disclosing noncompliance with its Code of Vendor Conduct globally, as identified by its Vendor Compliance Officers.¹⁴⁵ The company revoked approval of 70 factories (or 15 percent of the factories inspected) for violations, broken down into categories such as child labor or forced labor. In addition to its own Global Compliance department, Gap works with independent, third-party firms such as Verité, which performs supply chain monitoring and auditing, and Social Accountability International (SAI), which also manages the SA8000 supply chain certification standards.¹⁴⁶ Similarly, Nike in 2004 disclosed the names and locations of all of its contract factories worldwide.¹⁴⁷

Several collaborative organizations devoted to supply chain monitoring, such as the Ethical Trading Initiative (ETI) and the Fair Labor Asso-

ciation (FLA), have arisen to address human and worker rights violations on a structural, system-wide basis.¹⁴⁸ These organizations join companies, NGOs, and trade unions to advance industry-wide codes of conduct, accrediting programs, and public reporting mechanisms. Other certification schemes focus on specific issues and products, such as RugMark, which seeks to end child labor in the rug industry.¹⁴⁹

The same kinds of models can apply to product safety and toxicity measures in the supply chain. One of the companies that has come closest to this is Best Buy, whose corporate social responsibility report describes their **factory monitoring program** for company branded products. Third-party auditors examine social and environmental considerations at their factories.

In 2007 the company audited 100% of factories they did business with. Their report contains a month by month tabulation of whether audits found acceptable conditions, with ratings (percentages for 2007 in parentheses): "excellent (0%), acceptable (33%), conditional acceptable (54%), unacceptable (12%)." The company notes:

"We have learned that to truly influence change in factory practices, we have to meet our suppliers "where they are," and build program goals that are realistic and achievable in their settings over a set period of time. We are working with our current suppliers to set these milestones for improvement in their factory conditions."

The company notes that in 2007, the **highest levels of facility noncompliance were found in health and safety matters (41%)**. The level of transparency offered in this voluntary Corporate Social Responsibility report could prove an important model for companies in all sectors; including this important core data in their investor reports would be a further important innovation in transparency.

Reporting companies can and should do a better job of disclosure on these product toxicity issues. Companies can follow the leadership models from social issues auditing and reporting to provide added information on chemical supply chain issues including sources of materials, risk areas, and control systems. To enhance disclosure in financial reports, companies can clarify that the improved disclosure does not necessarily imply more risk than other companies whose disclosures are scant, but rather an initiative to apply disclosure duties in a manner that is intended to improve transparency and be more investor-friendly.

2. Investors can insist that companies do a better job of disclosure.

The Investor Environmental Health Network, publisher of this report, is a collaborative partnership of investment managers, advised by nongovernmental organizations, concerned about the financial and public health risks associated with corporate toxic chemicals policies. Through dialogue and shareholder resolution, IEHN encourages companies to adopt policies to disclose their toxic chemical risks and to work to systematically reduce and eliminate toxic chemicals in their products.

In the spring 2008 season, shareholder resolutions are pending at Dow Chemical (disclosure of policies regarding asthma-causing materials in Dow Chemical products), Avon (disclosure of policies on nanotechnology in products), and Circuit City and Kroger (disclosure of policies on toxic chemicals in products). Support for these resolutions is one way that shareholders can improve the state of disclosure of these product toxicity issues.

Institutional and individual investors in sectors with known toxicity issues such as chemicals, cosmetics and personal care products, home furnishings, and electronics need to request better disclosure from their portfolio companies. This can be done through direct communications with portfolio company managers, and through support of shareholder resolutions that seek such disclosure.

3. The SEC should issue a new guidance on product toxicity issues to improve corporate disclosure.

The SEC should issue new guidance in this area requiring companies to

- discuss and analyze recall and materials toxicity trends found in government regulatory databases, and their relevance to company supply chains and materials.
- promptly communicate, both internally and externally, information on supply chain management, including both specific problems as they emerge and any weaknesses in compliance assurance systems.
- characterize the portion of their product lines—as a portion of sales—that are Substances of Very High Concern (the products that may be banned or restricted in uses by European regulators). The potential for securing exemptions from the EU, given the high level of uncertainty regarding these outcomes, should not be a basis for avoiding providing this baseline analysis for product lines.
- report on credible new scientific findings indicative of potential product hazards, and to post the company's own scientific responses and defenses only after clearly describing information on credible, adverse scientific findings.

Epilogue: Bisphenol A in Baby Bottles and Other Products

In the two days before this report went to press, news broke regarding another potentially toxic chemical, bisphenol A (BPA). The chemical is used widely in baby bottles, canned food linings and sports water bottles, in a plastic known as polycarbonate. A US agency, the National Toxicology Program, issued a preliminary report that acknowledged for the first time the growing body of scientific literature evidencing BPA's hazards. These include cancer, developmental impairment, and reproductive system harm. Concurrently, The Globe and Mail, Canada's most prominent newspaper, reported that Health Canada, Canada's national health regulatory agency, would imminently recommend declaring BPA a dangerous chemical. Such a finding could lead to labeling and possibly restrictions on its use. This report prompted some of Canada's most prominent retailers to purge their shelves of BPA-containing products.

Though our report was already completed, we were interested in seeing how companies had addressed this emerging issue. Data on numbers of BPA studies published, generated for IEHN prior to filing of a shareholder resolution on BPA baby bottles at Whole Foods Market two years ago, tracked steady growth from 20 studies in 2000 to 32 in 2003 to 41 in 2004. Many of these were generating disturbing findings of health effects and, on this basis, Whole Foods Market, Inc. pulled baby bottles from its shelves. We used the SEC database to search producer and user industries for discussion of the emerging scientific literature documenting hazards of BPA, including searching for proximity of "bisphenol A" and "polycarbonate" to endocrine, health, liability, regulation and other related terms.

The four largest producers of BPA are Sunoco, General Electric Plastics,* Bayer and Dow

* General Electric sold its plastics division to SABIC in 2007.

BPA producers and users are likely to face rapidly changing markets for food and water contact uses, which could have been foreshadowed with ample disclosure of the surge in science finding problems with this chemical.

Chemical. None of these companies' SEC disclosures provided any discussion of the scientific issues concerning risks of BPA.

One other specialty chemical company had better disclosure of this issue. Hexion Chemicals noted in its 10-K for 2006 (March 22, 2007):

Bisphenol A ("BPA"), which is used as an intermediate at our Deer Park, Texas and Pernis, the Netherlands manufacturing facilities, and is also sold directly to third parties, is currently under evaluation as an "endocrine disrupter." Endocrine disrupters are chemicals that have been alleged to interact with the endocrine systems of humans and wildlife and disrupt their normal processes. As required by EU regulation 793/93/EC, BPA producers are conducting an extensive toxicology testing program of this chemical. In the event that BPA is further regulated, additional operating costs would be likely in order to meet more stringent regulation of this chemical.

Among companies using this chemical in the manufacture of goods, and retail companies selling products containing BPA, only one disclosure stood out, related to the shareholder

resolution filed at Whole Foods Market in 2006, which led Whole Foods to remove baby bottles containing BPA from its shelves more than two years in advance of the current surge in attention.

In contrast to the dearth of discussion of the emerging science evidencing risks of BPA, some financial reports and web postings contain various discussions of trends in the growth or decline of markets for BPA due to vaguely asserted market conditions. Such discussions could prove misleading without accompaniment by

information on the “dark clouds” on the horizon for uses involving contact with food or water.

BPA producers and users are likely to face rapidly changing markets for food and water contact uses, which could have been foreshadowed with ample disclosure of the surge in science finding problems with this chemical. This is further evidence of the need for improvement—better disclosure by companies, and better guidelines and enforcement by the Securities and Exchange Commission.

Endnotes

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- 2 Shawn Langlois, "Sherwin-Williams Stung by Ruling," *Marketwatch*, February 22, 2006; accessed April 28, 2006 at www.marketwatch.com
- 3 Merck Press Release, "Merck Announces Strong Financial Results for the Second Quarter 2006," July 24, 2006.
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- 5 Merck & Co, Inc., Annual report for the year ended December 31, 2007 (Form 10-K) at 17, February 28, 2008. In addition to the Vioxx Product Liability Lawsuits, various purported class actions and individual lawsuits have been brought against the Company and several current and former officers and directors of the Company alleging that the Company made false and misleading statements regarding Vioxx in violation of the federal and state securities laws (all of these suits are referred to as the "Vioxx Securities Lawsuits"). In addition, various putative class actions have been brought against the Company and several current and former employees, officers, and directors of the Company alleging violations of the Employee Retirement Income Security Act ("ERISA"). (All of these suits are referred to as the "Vioxx ERISA Lawsuits.") In addition, shareholder derivative suits that were previously filed and dismissed are now on appeal and several shareholders have filed demands with the Company asserting claims against the Board members and Company officers. (All of these suits and demands are referred to as the "Vioxx Derivative Lawsuits" and, together with the Vioxx Securities Lawsuit and the Vioxx ERISA Lawsuits, the "Vioxx Shareholder Lawsuits.")
- 6 Press release issued by New York State Controller's Office, "Hevesi Sues Merck & Co. Inc. Over New York Pension Fund Losses Related to Vioxx," November 30, 2004. The suit was dismissed by the District Court finding statute of limitations to have lapsed. In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig., 483 F. Supp. 2d 407, 2007 U.S. Dist. LEXIS 27123 (D.N.J. 2007). However the district court ruling was reversed by the 3rd Circuit Appellate Court of New Jersey. In re Merck & Co. Sec., Derivative & ERISA Litig., 493 F.3d 393, 2007 U.S. App. LEXIS 17000 (3d Cir. N.J. 2007).
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- 11 *Ibid.*
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- 14 Securities and Exchange Commission: "Certification of Disclosure in Companies' Quarterly and Annual Reports," 67 FR 57276 at 57279; available online at <http://www.sec.gov/rules/final/33-8124.htm>

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- 18 CPSC Release #05-278, September 22, 2005.
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- 21 Tammy Webber, "Indiana lead alert sparks U.S. recall; Lab tests: Toys' paint had up to 4 times legal limit", *The Indianapolis Star* (Indiana) Local-Metro & State p.1 August 18, 2006.
- 22 CPSC Press Release, "RC2 Corp. Recalls Various Thomas & Friends™ Wooden Railway Toys Due to Lead Poisoning Hazard," June 13, 2007; available at <http://www.cpsc.gov/cpscpub/prerel/prhtml07/07212.html>

CPSC defines "excess" level as "paint or paint and other similar surface coatings that contain more than 0.06% lead," among other criteria, and notes that "the scientific community generally recognizes a level of 10 micrograms of lead per deciliter of blood as a threshold level of concern with respect to lead poisoning." from, CPSC, "Guidance for Lead (Pb) in Consumer Products"; accessed January 30, 2008 at <http://www.cpsc.gov/BUSINFO/leadguid.html>
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Until 2002, RC2's "Product Safety" paragraph mentioned "product liability," which continued to appear in subsequent 10-Ks that also contained the additional paragraph on product liability and recalls. RC2 added about 50 words to this paragraph over the next few years, such as the sentence "A termination of a license could adversely affect our net sales."
- 29 RC2 Corporation, Annual Report for the year ended December 31, 2006 (Form 10-K), February 26, 2007, available at <http://www.sec.gov/Archives/edgar/data/1034239/000104216707000113/rc2dec312006form10-k.htm>

"Because we sell infant products, toys and collectibles to consumers, we face product liability risks relating to the use of our products. We also must comply with a variety of product safety and product testing regulations. If we fail to comply with these regulations or if we face product liability claims, we may be subject to damage awards or settlement costs that exceed our insurance coverage, and we may incur significant costs in complying with recall requirements. In addition, substantially all of our licenses give the licensor the right to terminate if any products marketed under the license are subject to a product liability claim, recall or similar violations of

product safety regulations or if we breach covenants relating to the safety of the products or their compliance with product safety regulations. A termination of a license could adversely affect our net sales. Even if a product liability claim is without merit, the claim could harm our reputation and divert management's attention and resources from our business."

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- 55 The guidance is available at http://reach.jrc.it/docs/guidance_document/svhc_en.pdf, p. 53, and provides criteria for evaluation of persistence, bioaccumulation, and toxicity:

1.1 Persistence

A substance fulfils the persistence criterion (P-) when:

- the half-life in marine water is higher than 60 days, or
- the half-life in fresh or estuarine water is higher than 40 days, or
- the half-life in marine sediment is higher than 180 days, or
- the half-life in fresh or estuarine water sediment is higher than 120 days, or
- the half-life in soil is higher than 120 days.

The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which shall be described by the registrant.

1.2 Bioaccumulation

A substance *fulfils* the bioaccumulation criterion (B-) when:

- the bioconcentration factor (BCF) is higher than 2000.

The assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.

1.3 Toxicity

A substance *fulfils* the toxicity criterion (T-) when:

- the long-term no-observed effect concentration (NOEC) for marine or freshwater organisms is less than 0.01 mg/l, or the substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3), or there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.

- 56 The EPA PBT Profiler website notes that: "The PBT profiler uses a well-defined set of procedures to predict the persistence, bioaccumulation, and toxicity of chemical compounds when experimental data are not available. The only user-required inputs for the PBT profiler are a unique identifier (e.g., a CAS Registry Number, product ID, or acronym) and a chemical structure. Chemical structures are entered into the PBT profiler using a SMILES notation. Weininger, D. SMILES, A Chemical and Information System. 1. Introduction to Methodology and Encoding Rules. *Journal of Chemical Information and Computer Sciences* 28: 31-6 (1988)]. An automatic look-up function based on the CAS Registry number simplifies this process by automatically retrieving a chemical's SMILES notation using a pre-existing database containing over 100,000 records. The chemical structure is then passed to nine separate physical/chemical property estimation modules, and the results are converted electronically to a persistence, bioaccumulation, and toxicity value.... The persistence, bioaccumulation, and fish chronic toxicity values estimated by the PBT profiler are automatically compared to criteria published by the EPA. Those values that meet or exceed the criteria are flagged for the user on the PBT Profiler results page. When estimations meet or exceed criteria, that material should be evaluated as a potential PBT Chemical.

- 57 "SVHC (Substances of very high concern) can be authorised if the CSA demonstrates that the use of a substance can be 'adequately controlled'. However, this route is not available for PBTs, vPvBs and nonthreshold CMRs (i.e. when it is not possible to determine a threshold in accordance with REACH Annex I, section 6.4). A review will be completed by 31 May 2013 to consider if endocrine disruptors should also be excluded from the 'adequate control' route. For those SVHC where 'adequate control' cannot be demonstrated or this route is not available an authorisation can still be considered on the basis of a socio-economic assessment. All applications for an authorisation must be accompanied by an analysis of possible alternatives considering their risks and the technical and economic feasibility of substitution. If a suitable alternative is available a substitution plan must also be included in the application. If no alternatives are identified, a research and development plan should be instigated if appropriate." Andrew Fasey, "REACH is Here. The Politics are Over, Now the Hard Work Starts." Lowell Center for Sustainable Production, p. 13; available at <http://www.chemicalspolicy.org/downloads/REACHisHere220307.pdf>
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