



Precautionary Preference

How Europe's New Regulatory Protectionism Imperils American Free Enterprise ©

by

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EXECUTIVE SUMMARY

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I. INTRODUCTION:

EUROPE AS THE NEW GLOBAL REGULATOR

U.S.-based businesses of all sizes, but especially small and medium sized businesses will, over time, likely be subject to more stringent environment, health and safety ('EHS') regulations and related technical product standards. Whether they know it or not, many of these rules will have originated within the European Union ('EU') without their constructive input or consent – 'regulation *without* representation'.

Indeed, as reflected in official EU policy documents, the products covered by these regulations, directives and standards "represent a large proportion of [all] products that are placed on the market. It is estimated that, as of 2003, the trade of products covered only by the major [agricultural and industrial] sectors regulated...largely exceeds the volume of 1500 billion euro (1.5 trillion euro) [(or approximately \$2.25 billion)] per year." Given the breadth and reach of these regulations and standards, the U.S. business community should be alarmed, no matter the sector (goods or services) in which they operate and no matter where they design and manufacture their products.

A growing number of these EHS regulations and product standards are based on an evolving international legal norm known as the 'precautionary principle'. The precautionary principle is essentially a non-scientific, 'better safe than sorry', risk-averse philosophy of regulation. It has already assumed the status of regional law within Europe, and European regulators and environmental groups are eager to establish it as an international and a U.S. legal standard.

The aim of this paper is to highlight how European environmental, health and safety regulators have imposed hundreds of very costly precautionary measures and controls on business conduct, the nature of these regulations, and how they adversely affect U.S. enterprises doing business internationally (within Europe *and* third countries, including China). It also discusses how such hazard-based, rather than science/risk-based, regulatory controls are becoming increasingly popular in the U.S., and how our economic competitors would benefit from the widespread export of precautionary principle-based regulations to America, thereby laying the legal groundwork for new disguised trade barriers.

In particular, this study points out the high business and legal costs borne by European companies in comparable industry sectors, as well as, the chilling effect these regulations have had on European research and development, capital investment and technological innovation. It also discusses how precautionary principle-based regulatory changes would profoundly impact, in a negative way, several areas of U.S. law beyond environmental, health and safety, namely tort, insurance, corporate, and securities law. Furthermore, the study discusses how the EU, with assistance from European and American environmental non-governmental organizations ('ENGOS'), has already begun to inject similar rules into U.S. law. Thus far, this effort has been limited mostly to state and local initiatives, though a number of state attorneys general have filed suit against the U.S. Environmental Protection Agency over the issue of global climate change. There are also various efforts underway to review federal environmental, food, drug and chemical regulations that precautionary principle advocates believe fail to ensure a high enough level of public safety.

The paper additionally identifies how U.S. companies have increasingly fallen subject to the relatively new but growing ENGO discipline of 'supply-chain management', which is an outgrowth of the global corporate social responsibility ('CSR') movement. With guidance and assistance from the EU Commission and United Nations Global Compact Office, Environment Program, and Commission on Sustainable Development, ENGOS and social groups have developed and imposed on U.S. multinational

companies and their small and medium-sized suppliers the duty/obligation to comply with extra-legal, morals-based CSR standards. These standards generally demand that companies act in a socially and environmentally responsible manner consistent with the precautionary principle, in excess of legal requirements, no matter where they conduct their business. These standards also require that multinational companies and their suppliers submit to audits and verification by *private* third parties – ‘global stakeholders’ (ENGOs and social groups, not stockholders or debt-holders) – and that they publicly report their CSR activities annually.

II. WHAT IS THE PRECAUTIONARY PRINCIPLE?

A. Evaluates Hazards Rather Than Risks

Pursuant to the precautionary principle, government regulators need not prove objectively through empirical scientific risk assessment, actual exposure data, and probabilistic computations (extrapolated safety factors) that a particular substance or product is likely to cause actual harm within a foreseeable period of time to a specifically identified population or ecosystem. Rather than focus on the probable occurrence of actual risks under real life circumstances (i.e., with reference to use and exposure), the EU Commission and European environmentalists have promoted a new paradigm that effectively shifts the subject of evaluation from actual risks to hypothetical hazards. Regulators need simply to identify a product’s or substances’ inherently dangerous characteristics or intrinsically harmful qualities and to rely upon an administratively-created presumption of possible harm.

B. Dispenses With Economic Cost-Benefit Analysis

In addition, EU regulators who employ the precautionary principle and their environmental and political allies have dismissed the need to undertake an economic cost/benefit analysis that is required by U.S. law for many types of regulations. Cost-benefit analysis is utilized by the U.S. government as a safeguard to ensure an equitable balancing of important societal interests, including those of industry. In fact, the legal adviser to the EU Commission has spoken out strongly against the use of economic cost-benefit analysis, alleging that “[c]ost benefit analysis and other influences can lead to undue delays in precautionary action and further losses.”

C. Generates Fear and False Perceptions that Lead to Risk Aversion

European regulators focus less on objective scientific evidence when evaluating public risks and more on subjective nonscientific criteria based on abstract notions of ‘morality’, ‘social justice’ and ‘quality of life’ rooted in unfounded perceptions of risk. These perceptions are generated by politically active and ideologically motivated environmental and consumer groups and like-minded politicians, who demand that regulators eliminate from society *all* health and environmental risks. The ideological ‘concerns’ of these influential non-governmental organizations (‘NGOs’) are raised to the level of ‘public’ consciousness via misinformation and fear campaigns that so exaggerate the presence of hypothetical hazards that perceived risks have become more important than *actual* risks in the public’s mind. Unfortunately, many European companies have found out the hard way how the irrational fear of risk-taking (risk aversion) curtails economic growth and technological innovation, and adversely affects societal well-being and quality of life.

III. HOW DID THIS OCCUR? – IT BEGINS WITH HEALTH AND THE ENVIRONMENT AND ENDS WITH TRADE

A. The Crafting and Packaging of a Regional EHS Policy Message

Because of the significant political influence wielded by these civil society groups within Brussels and European capitals, EU regulators have had to respond to their concerns. Indeed, pro-environment EU regulators have enlisted the assistance of these groups for the purpose of developing a regional public policy premised on notions of morality that calls for higher regional and global EHS protections. That policy essentially rejects U.S. scientific and technical innovations, economic efficiencies and free markets (i.e., globalization). It also rejects the U.S. legal benchmark of economic cost-benefit analysis, which it claims has become a politically charged, illegitimate process that has been adeptly manipulated by American industry to prevent the adoption of necessary U.S. EHS regulation.

B. Incorporating Regional EHS Policy into the International Trade System

In order to exploit this regional policy for purposes of international trade, European regulators have endeavored to promote on a global level the same very close link between EHS regulation (government policymaking) and ‘top-down’ (rather than industry-driven) product, process and service standardization that they have already established at the European regional level. The discipline of standardization serves an important role within Europe – it helps to translate essential environment, health and safety regulatory and policy requirements into understandable technical guidelines which businesses may then use to design, manufacture, formulate, assemble and dispose of their products. In the words of former EC Enterprise Commissioner Erkki Liikanen, EU regional standards have also “offered [the EU] a systematic framework *to take over* international standards and/or to contribute to the international standards-making process” (emphasis added). And, according to Wolfgang Clement, German Federal Minister of Economy and Labour, “standardization is...extremely relevant for the individual participants in economic processes, *since whoever makes the standards controls the market*” (emphasis added).

C. Establishing the Political and Moral Legitimacy of European EHS Policy

In an effort to link the political and moral dimensions of European international trade policy with the real economic dimensions of international trade, the EU Commission has sought to update WTO rules. Hence, it has endeavored to convince other WTO members of the political expediency of incorporating their own societal and environmental values/ preferences within national and regional regulations and standards even if they may have the effect of restricting international trade. Thus far, this has permitted the EU to justify its imposition of precautionary principle-based regulations and standards upon EU trading partners. According to former EU Trade Commissioner (and now WTO Director General) Pascal Lamy, mutual respect for national cultural preferences falls within the notion of ‘mutually balanced concessions’ that underlies the quid pro quo achieved long ago under the General Agreement on Tariffs and Trade (GATT).

D. Using EHS Policy as a Disguised Trade Barrier

Europe’s strict EHS policies based on the precautionary principle have an added *economic* dimension. Ailing, lagging or underdeveloped European industries, overwhelmed by significantly higher regional regulatory, standardization, labor and energy costs and starved from a steady reduction in regional research and development investment, are no longer globally competitive. Unable to prevent the proposal and adoption of precaution-based regulations regionally, European industry has to assist EU regulators

and civil society in establishing the precautionary principle as an absolute global legal standard by exporting it around the world, especially to the United States. This strategy has conveniently served to ‘protect’ European industry’s global economic interests by generating generally higher business and legal costs, which all industry supply chains throughout the world must bear.

IV. EXAMPLES OF EU PRECAUTION-BASED EHS REGULATIONS

There are numerous examples of European precaution-based regulations that reflect the use of an administrative presumption of hazard to ban or severely restrict the manufacture and use of certain products, substances and activities, irrespective of actual health or environmental risks. They include newly enacted rules on biotech products, toxic and high volume chemicals and downstream products, cosmetics, e-waste disposal and recycling, brominated fire retardants, product life cycle management and climate change.

V. THE HIGH COSTS OF PRECAUTIONARY PRINCIPLE-BASED REGULATION

A. Compliance, Intellectual Property and Misrepresentation Costs

Precautionary principle-based regulations, directives and related product standards engender significant compliance costs. They require companies to develop and submit detailed information dossiers about the composition and processing of products in which sensitive technical information and formulae and intended product uses are disclosed. In addition, they require the sharing of such confidential information among all producers, intermediaries, and distributors present along a product’s vertical supply chain. Furthermore, in each case, there is little regulators have afforded in the way of intellectual property right protection for valuable company intangible assets. And, they require detailed and costly product labeling, consistent with strict national and regional ‘consumer right-to-know’ laws, whether or not consumer safety issues are involved, and irrespective of whether the environmental performance claims made on those labels can be scientifically/technically achieved.

B. Eco- and Social Labeling and the Costs of Brand Reputation

Precautionary principle-based regulations reflect an effort by the EU to foster artificial product and process distinctions and to create consumer expectations in the marketplace that will negatively affect the competitive conditions of non-EU products. In effect, Brussels is acting as a market ‘maker’ rather than as a market ‘facilitator’ of European consumer preferences in the absence of a general market demand for environmentally friendly products and services. The EU’s labeling rules concerning GMOs, electronics and electrical equipment, toxic chemicals, cosmetics and biocides provide such an example, as does the more recent EU furniture eco-label program.

C. Tort Liability Costs

If the precautionary principle became a formal U.S. legal standard, companies would be obliged to satisfy a broad, affirmative, forward-looking legal ‘duty of care’ as a precondition to securing market authorization and market access for their products. In that event, companies would need to ensure that the manufacturing methods they employ and the potential uses to which their products or substances are

ultimately placed, even if presently unknown, will have as minimal a health and environmental impact as possible (without regard to ‘reasonableness’), irrespective of the costs to industry.

Within the transformed U.S. tort system precautionary principle advocates envision, legal liability would be triggered merely as the result of a *prima facie* breach of a broader obligation/responsibility imposed by *civil* law, and the failure to satisfy a greater evidentiary burden of proof normally imposed under the *criminal* law. Thus, liability for violation of precautionary principle-based regulations would be premised on, but would go beyond the U.S. common and statutory law of negligence, strict liability, ‘products liability’ and public nuisance. A case in point is Articles 5 (‘Preventive Action’) and 8 (Prevention and Remediation Costs’) of the recently enacted EU Commission Directive on Environmental Liability, which implements the EU ‘polluters pay’ principle.

Furthermore, were the precautionary principle to become U.S. law, it would shift the legal burden of proof from government to industry by requiring that industry produce a sufficient quantity of testing evidence that *also* qualitatively persuades government regulators of a product or substance’s ‘safety’ or ‘harmlessness.’ In essence, industry would need to overcome a higher threshold of persuasion (legal standard of proof) than that currently called for in civil litigation within the U.S. (i.e., ‘proof beyond a reasonable doubt’, as found in U.S. *criminal* litigation, rather than ‘proof by preponderance (or balance) of the evidence’). This would, in effect, create a rebuttable presumption (an inference) of negligence in favor of the plaintiff with merely the presentation of circumstantial evidence of the defendant’s failure to act reasonably, consistent with the disputed legal doctrine of *res ipsa loquitur*.

Moreover, American technology developers, product manufacturers and designers and substance formulators would be prevented from claiming that they had exercised reasonable care by following then-prevalent ‘customary industry practices’ or ‘state-of-the-art’ technical/scientific standards, when responding to a products liability or toxic tort action based on negligence or strict liability. The so-called ‘state-of-the-art’ defense, if applicable, would exempt a producer from liability where the state of scientific or technical knowledge at the time the product was marketed made the defect in the product undiscoverable. If this defense were removed, producers would be held liable “for defects in their product that could not be discovered at the time the product was marketed.”

The duty to exercise ‘precaution’ during the course of one’s activities to the extent they involve a *foreseeable risk to foreseeable parties* seems already firmly entrenched within the U.S. case law on negligence. In addition, courts have imposed on parties a duty to exercise precaution to prevent the negligent acts of third persons from causing *foreseeable* harm to others, especially if serious risks of harm are likely to occur. The adoption of the precautionary principle by U.S. federal and state regulators, however, would arguably serve to overrule U.S. case law. It would extend the duty to exercise precaution to new activities and parties for purposes of preventing suspect substances, products and technologies from causing *unforeseeable* harms to the public at large.

D. Insurance Costs Related to Development Risk

Insurance law experts also have noted the potentially adverse impact that the precautionary principle would have on the current U.S. insurance system. That system is based on the late nineteenth century social paradigm of ‘solidarity-based governance’, which has prevailed in the U.S. since the New Deal era. It sought to address the problem of industrial work accidents by providing truly innocent victims with compensation without regard to assessment of fault. It also promoted the “sharing of risks across society in the name of reducing the overall suffering of the population[,]...recognized accidents as ordinary features [risks] of modern life to be actuarially predicted[,]...and ameliorate[d] systematic losses through technology and [balanced] regulation.”

Precautionary principle advocates seek to replace that system with a new ‘safety’ paradigm of prevention. The safety paradigm focuses on new types of catastrophic environmental threats that loss spreading and balanced regulation would arguably be unable to address. These include global warming and the potential impact of hazardous chemicals and biotech foods. According to at least one insurance law expert, such thinking “threatens an U.S. insurance system that is based on the idea that insurance” involves fixed premiums paid in advance for guaranteed benefits in the event of loss.” In his opinion, this would precipitate a fundamental systemic change that would entail the incorporation by insurers of ‘post-loss assessments’ into their insurance contracts.

This means, in effect, that the cost of insuring against possible future catastrophic losses would no longer be based solely on fixed premiums. Rather, such cost would also depend on the levy of an additional charge following the occurrence of a catastrophic event that is determined based on a final assessment of the resulting damages. And, these costs could conceivably multiply in the absence of a reliable post-loss assessment mechanism. This expert believes that drugs and other health technologies present two specific cases where the current insurance system’s failure to adequately address ‘development risk’ will ultimately result in greater regulatory and insurance costs. “Development risk [is] the risk that a product will produce a kind of harm that is not foreseeable at the time of design but for which the manufacturer is liable under the principle of strict liability.”

The real concern, however, is that the public and media hysteria created by successful environmental NGO fear campaigns will exacerbate the losses already suffered, and cause the “uncompensated victims to clamor for criminalization of environmental law and to call for [more] extreme [regulatory] efforts to prevent loss in the future.” Some legal academics have proposed an alternative mechanism to facilitate the shift from public risk bearing to private risk bearing (internationalization of potential environmental externalities) called for by the precautionary principle — the requirement of costly assurance bonds.

Although multinational corporations could arguably absorb the expense of posting an assurance bond, small and medium sized companies would likely be devastated if compelled to do so. The cost of bonding would likely be disproportional to the size of most SMEs in terms of employment, sales revenues generated and the contract value of activities engaged in.

E. Insurance Costs Related to Climate Change

The consulting arms of mostly European reinsurance companies are busily advising multinational companies of the need to mitigate their potential exposures to environmental liabilities and financial costs surrounding climate change risks. At least one American academic has estimated that “\$2.7 trillion of the \$10 trillion U.S. economy is susceptible to weather-related loss of revenue related to climate change.

But, a closer look at European reinsurance company activities reveals what they are really after. They are seeking to avoid or mitigate their own liability for possible future direct and indirect reinsurance losses to which they are subject under their current insurance and reinsurance contracts. Initially, this can be accomplished by spreading the potential insurance and financial risks and higher related costs to their American competitors, and ultimately to their American clients. European reinsurers can also hope to influence human settlement patterns and catastrophe risk management practices through risk-adequate insurance rates.

European reinsurance companies have sought to reduce their primary insurance and reinsurance property and casualty coverage of new policies that secure existing or newly planned commercial and residential real property assets located along densely populated, storm-prone European and U.S. coastlines. These limited and reduced coverage policies are likely to negatively impact property development, reduce the pool of available insurance funds, and drive up national and regional insurance rates beyond the reach of many European and U.S. property owners.

As a result, remaining owners will then be forced to bear catastrophic losses from natural disasters on their own (with limited or no insurance), and arguably this will lead them to demand immediate government action to cover their losses. That action will likely entail holding greenhouse gas ('GHG') 'polluting' industries responsible for their past GHG emissions pursuant to a precautionary principle-based strict liability regime, and governmental enactment of stringent hazard-based regulations to restrict GHG emissions in the future.

However, because "it is difficult to quantify the actual and future [long-term] direct impacts of climate change on catastrophe losses", European reinsurers have instead focused most of their attention on the more expensive shorter-term indirect risks, namely, regulatory risks. European reinsurers have conveniently conveyed to industry how indirect regulatory risks can necessitate new insurance products that will ultimately be subject to coverage limitations. For example, they have alerted corporate directors and officers of the growing risk that they may be subject to liability from shareholder derivative suits for failing to effectively manage their company's carbon emissions consistent with GHG emission regulations.

F. D&O Liability and the Business Judgment Rule

European-based international reinsurance companies are putting their multinational clients on notice about the potential D&O liability they may incur under U.S. common law because of their directors' and officer's actions *or* inaction. Such 'covered' liability could be triggered, for instance, as the result of a board's gross negligence in rendering a business decision. Alternatively, it could attach as the result of a board's failure to remain adequately informed of and attentive to available and relevant information which could help it to decide how to mitigate company environmental litigation and regulatory risks, such as those that may be related to global climate change. Reinsurers may also be admonishing companies that their D&O policies may, in the future, no longer cover director liability for breaches of the fiduciary 'duty of care'.

In effect, these reinsurers are focusing U.S. corporate attention on the corpus of available and relevant information for which directors and officers of public companies should be held responsible in the future. This includes knowledge of the myriad activities conducted by their many small and medium-sized suppliers/contractors/agents. In their view, this would motivate companies to develop and implement internal governance systems that can track and promote more environment-friendly supply-chain management practices consistent with sustainable development. In other words, it would force U.S.-based multinationals to dictate how their small and medium-sized suppliers should conduct their daily business operations.

Pursuant to such a requirement, directors and officers would also need to remain informed about emerging foreign regulatory trends and product standards, policies, and proposals, and to keep current regarding the status of ongoing intergovernmental regulatory and standards processes. D&O liability could thus arise in the absence of such knowledge, where it is shown that the board's inattentiveness or indecision prevented it from taking measures to reduce company climate change risk which, in turn, results in regulatory violations and a significant economic loss to the company.

Furthermore, precautionary principle advocates and environmental investors would like to extend such a broad knowledge mandate to other company activities deemed intrinsically hazardous to human health or the environment – even in the absence of scientific proof of possible harm or governmental action. By putting companies on notice about the potential hazards posed by their continued production and/or use of chemicals deemed hazardous and the products containing or processed with them, or by pharmaceuticals, cosmetics or genetically-modified organisms ('GMOs'), a board would be hard pressed not to establish an extensive internal process of information-gathering. Under penalty of potential

liability, they would have to engage in a regular pattern of decision-making that would raise issues related to product design, manufacturing, servicing, reclamation, recycling and/or disposal (i.e., product stewardship in the auto, appliances, electronic and electrical equipment and computer industries).

In each case, if director ignorance, inattentiveness or indecision results in a failure to consider and/or act against potential future regulatory liability and related economic loss, corporations, directors and officers could not rely on the ‘business judgment rule’ (‘BJR’) as a legal defense. Pursuant to this common law doctrine, courts have typically deferred to the business judgment of directors, as long as they have *acted* in good faith, with loyalty to the corporation and on an informed basis (with care). Implicit within this defense is the recognition that not all director decisions will benefit the corporation or appear to be prudent. Courts will not second-guess business decisions by directors *provided the directors follow appropriate procedures in making the decision*. This is precisely the message that has been indirectly conveyed by private ‘sustainability’ indexed and mutual funds and socially and environmentally focused state pension and investment funds through their filing of shareholder resolutions.

However, the line between the exercise of gross negligence in rendering a board decision and the absence of a conscious decision (indecision/inattentiveness) and failure to act is a fine one. This is especially true, where reasonable persons could disagree about the relevance, veracity and usefulness of available information, particularly, whether it should serve as the basis for corporate action or inaction. Also, there are often instances where the law is unclear on its face, where there is doubt about how it will be implemented, or where uncertainty exists as to whether a legislative proposal will ultimately be adopted.

In light of the evolving BJR case law, while courts may not, except under extraordinary circumstances, review board of directors’ *substantive* business decisions, they have become more proactive in reviewing the information gathering and review processes, (i.e. the internal governance mechanisms), upon which those decisions may ultimately be based. In one recent high profile case, the Delaware Chancery Court held that where a director fails to ‘exercise *any* business judgment or to make *any* good faith attempt to fulfill (i.e., where a director consciously ignores) his or her duties to the corporation (by adopting a ‘we don’t care about the risks’ attitude concerning a material corporate decision), and that failure causes economic injury to company stockholders, the director’s actions are either ‘not in good faith’ or involve ‘intentional misconduct’”, and are thus subject to liability. Some legal experts have advised that this case “has the potential to raise the [substantive common law] legal standard to which directors must adhere...[i.e., the fiduciary duty owed to the corporation]...to avoid personal liability.”

G. The Encroaching Sarbanes-Oxley and SEC Disclosure Rules

The business judgment rule focuses mostly on ensuring that the necessary information gathering processes and internal governance systems upon which boards may rely to make informed business decisions in the best interest of corporations and their shareholders are put into place. It does not address the kinds of information that the board should deem relevant for consideration or the substance of board decisions based on that information. It also does not address whether the board need disclose such information to shareholders. The Sarbanes-Oxley Act, a federal statute, instead looks to the kinds of information that boards must consider (e.g., corporate ‘risks’), and requires companies, as a matter of corporate governance, to publicly disclose the impact of such risk information in their periodic company financial statements.

However, social and environmental groups that support the precautionary principle are not yet satisfied that Sarbanes-Oxley and current SEC disclosure rules go far enough to ensure a ‘true and accurate’ financial accounting and disclosure of existing *and potential* corporate environmental liabilities.

And, they and their congressional and UN allies have already endeavored to persuade the SEC to change those rules so that they do. In fact, these groups are largely behind the corporate accountability movement, which seeks to make SEC financial disclosure rules more stringent and transparent. Their goal is to discern out which companies and supply chains are not taking appropriate measures to address climate change risk for purposes of targeting future disparagement campaigns and shareholder resolutions against them.

VI. EUROPEAN INDUSTRY'S EXPERIENCE WITH HIGH COST PRECAUTIONARY PRINCIPLE-BASED REGULATIONS

A. Overall

The administrative, financial and legal burdens imposed by EU precaution-based environmental regulations has been found to be equivalent to a hidden business tax that, as of 1999, constituted as much as 15% of the new capital invested by certain European industry sectors. These costs are likely to comprise a much higher percentage of such funds in 2005. Unfortunately, as European businesses have discovered, it cannot be assumed that the increased costs of design, retooling, production and waste disposal incurred as the result of precaution-based regulations can be passed along the supply chain unnoticed to their business customers and to the ultimate consumer. In other words, they found that they had to be internalized (i.e., self-absorbed), especially during lean economic times. Consequently, the profitability, competitiveness and viability of European small and medium-sized enterprises ('SMEs') have been severely threatened. For example, the European media and European industry associations have reported how generally higher European labor and precaution-based environmental regulatory costs have had a negative impact upon German corporate research and development investment and technological innovation.

B. Forest-Based Industries

The EU Commission has determined, for example, that, far from enhancing the competitiveness of Europe's forest-based industries, the relatively higher cost of precautionary regulation, when coupled with higher related energy and labor costs, actually made these companies *less* competitive globally.

C. Pharmaceuticals and Life Sciences

Similarly, greater EU research and development, clinical testing and regulatory authorization costs have primarily contributed to higher pharmaceutical production costs and lower pharmaceutical industry profitability. And, when combined with European national laws constraining pharmaceutical prices, profit margins and intellectual property protection, these costs have posed a serious obstacle to maintaining the competitiveness of European pharmaceutical and biotech products. As a direct result of these higher costs and profitability constraints, European pharmaceutical companies have found it increasingly difficult to attract the investment capital necessary to fund their research and development activities, and consequently, have had to curtail such spending. This, in turn, has had a dangerous 'chilling effect' on European industrial and technological innovation and it has cost European pharmaceutical companies their competitive position vis-à-vis US companies. It has also caused many such companies to relocate to the more business-friendly climate of the United States.

D. Chemicals and Downstream Industries

The European chemicals sector appears to be at a comparative disadvantage relative to the U.S. chemicals industry, due to both higher regional energy costs (triggered, in part, to the anticipation

surrounding Kyoto Protocol emissions caps) and the likely adoption of costly European precaution-based chemical regulations (REACH). Several European industry studies have forecasted significant declines in economic output and employment throughout Europe as the result of the enactment of such precautionary principle-based regulations. Consequently, the EU chemicals sector now finds it difficult to maintain sufficient research and development spending within the European region, and has increasingly chosen to relocate plant, equipment and R&D to less costly developing countries such as China.

VII. PRECAUTIONARY PRINCIPLE-BASED REGULATIONS EXPORTED TO CHINA

China has within the last ten years become the factory of the world and is now widely recognized as the base of the global supply chain for many types of manufactured products and processes. It is for this reason that the pace of joint EU-China regulatory and standards initiatives has increased in recent years. Unfortunately, those activities may also have a significant adverse impact on the China-based imports *and* exports of U.S. companies.

Since 2000, the EU has maintained a science and technology exchange program (the ‘INCO Programme’) based in China to promote EU health, environment and food security and safety research. Its goal has been to move China towards European precaution-based regulatory rules in order to impose them throughout the global product supply chains. In many ways, the EU has already achieved considerable progress. And these official ‘capacity building’ efforts have been complimented by those of the ENGO community, which is involved in developing China’s environmental regulatory framework so that it incorporates the precautionary principle and impacts global supply chains. What has concerned American companies even more regarding China’s growing cooperation with Europe on legislative, regulatory and standards issues, however, is its willingness to emulate Europe’s use of strict top-down (precautionary principle-based) environmental regulations as disguised trade barriers in order to protect its nascent commercial and technology-based industries.

VIII. PRECAUTIONARY PRINCIPLE-BASED REGULATIONS PROPOSED AND ADOPTED IN THE U.S.

The American media last year reported about the growing collaborations taking place between the American and European environmental and corporate social responsibility (‘CSR’) movements. It noted how American groups are devoting substantial financial and human resources to European-based fear campaigns that intimidate Brussels Commissioners and Parliamentarians, sway European public opinion, threaten the reputations of non-environmentally or socially conscious businesses, and ensure the enactment of legislation based on the precautionary principle.

According to these reports, such non-governmental organizations (NGOs) are now using the stricter precaution-based European regulations as a lever/ platform to promote similar regulatory change in the U.S. Apparently, this movement has been assisted by liberal-minded American think-tanks and misinformed politicians from both political parties. This alliance has enabled precautionary principle advocates to take more aggressive and direct action by introducing legislation and initiating legal challenges at the local, state and federal levels, thereby “challenging the very way America does business”. In fact, some within the federal government have long feared that, if Europe’s global precautionary principle movement were successful, it could eventually change U.S. domestic regulatory law.

B. Sector-Based State and Local Legislative Initiatives

1. *Hazardous Substances and Waste Product Disposal*

Within the past five years, numerous state legislatures have enacted or otherwise reviewed precautionary principle-based proposals seeking to ban or severely restrict the use and disposal of hazardous waste substances consisting primarily of electronic waste ('e-waste' – scrap metal and plastics), batteries and brominated flame retardants used in fire extinguishers, and in the manufacture of clothing and furniture.

2. *Cosmetics*

A bill modeled after the EU cosmetics regulation was recently introduced in the California legislature during 2004. The bill "was intended to ban cosmetic or personal care consumer products containing chemicals identified as causing cancer or reproductive toxicity. Although the bill was defeated, amended, reintroduced and then defeated again, supporters have vowed to bring it back in a different form during 2005.

3. *Toxic and High Volume Chemicals*

During 2003, a "group of scientists, public health advocates, labor unions and environmental advocates" introduced a bill in Massachusetts to reduce the use of toxic substances. Based largely on the EU proposed REACH regulation, the bill "would require substitution of 10 priority chemicals where safer alternatives exist." This broad coalition supporting the legislation – the "Alliance for Healthy Tomorrow" – was formed to develop precautionary policies to address toxic substances and other perceived 'evils' such as global climate change and genetically modified (GM) food.

As recently as January 2004, "the California legislature requested that the University of California, [Berkeley] investigate chemicals policy options [including the EU REACH regulation premised on the precautionary principle] for California and recommend a model for adoption" for improving the management and regulation of chemicals within the state. Apparently, like-minded environmental advocates from Massachusetts have joined efforts with California environmentalists in lobbying their legislators to 'import' EU precautionary principle-based chemicals management standards into the United States.

4. *Biotech Foods – State and Local Initiatives*

During the past several years, different constituencies have endeavored at the state level to prevent the widespread proliferation of biotechnology within the U.S. food chain. The legislation proposed within a number of states has been based on varying rationales, some consumer choice-focused (e.g., notification & labeling), some food safety-focused (e.g., concerning pharma and biopesticide-resistant crops and fish), some environmental focused, and still others economics-focused (e.g., concerning lost organic export trade to Japan and Europe in the absence of GM-free certification). Additional legislative proposals have sought to impose liability on farmers and/or GM seed companies for GM crop contamination. And, more recent local initiatives advanced by anti-biotech advocates and organic farmers, which employ a 'divide and conquer' strategy, have successfully persuaded some farmers to promote 'farmer protection' proposals that effectively place ALL legal responsibility for crop contamination with the seed and drug companies.

5. *Climate Change*

During the past decade, a number of states have passed legislation establishing greenhouse gas (GHG) registries and carbon reporting requirements. Several other states meanwhile have enacted laws that regulate carbon dioxide (CO₂) as an air ‘pollutant’ along with other GHGs deemed to contribute to global warming. Although California may appear to be the most forward-looking jurisdiction as regards ‘climate change’ legislation, it is actually the northeastern states, led by the Republican governors of New York and Massachusetts and the regulatory stronghold of New Jersey, that have aggressively pursued an innovative but highly controversial regional approach to addressing GHG emissions. In fact, six New England governors have already entered into a Kyoto-like “compact with five Eastern Canadian Premiers to reduce regional GHG emissions to 1990 levels by 2010 and 20 percent below 1990 levels by 2020.”

The Regional Greenhouse Gas Initiative (RGGI) was conceived by New York State Governor George Pataki, during 2002, and a model agreement (compact) evidencing the commitment of eight other northeastern states and five adjacent Canadian provinces to be bound by this precedent-setting regional initiative is scheduled to be executed this coming fall. In addition to imposing a mandatory cap on the carbon dioxide emissions of locally-based power plants in each of the participating states, RGGI would also entail the establishment of a regional GHG registry and an emissions trading scheme similar to the precautionary principle-based carbon dioxide emissions trading scheme recently enacted within the EU region.

Arguably, RGGI remains inimical to U.S. economic interests for a number of reasons. First, it is clear that such a regional initiative, by itself, will have no measurable scientific and environmental impact (benefit) on global warming – i.e., it is merely a political and symbolic undertaking. Second, the RGGI, as structured, *will* regulate and effectively tax (via a process-based levy) interstate commerce - energy imported by power plants into the RGGI region from non-RGGI states to prevent ‘leakage’. Third, despite official state government assertions and modeling assumptions to the contrary, candid discussions with RGGI government stakeholders and media reports have revealed that significantly higher business and consumer energy prices can be expected for at least the following ten year period – i.e., until 2015.

Fourth, the RGGI will contravene U.S. federal climate change policy. The U.S. Congress has not yet adopted federal legislation regulating carbon dioxide or other GHG emissions, and the Bush Administration has affirmatively renounced America’s prior signature to the Kyoto Protocol. Fifth, no matter what RGGI government stakeholders publicly claim, the RGGI *will be international* in scope, and thereby potentially affect U.S. foreign policy and give rise to several U.S. constitutional challenges. For example, it may likely be found to violate the U.S. constitutional law doctrine of federal preemption and the interstate commerce clause. It may also substantially impair the plenary authority of the President and the Congress over foreign affairs, including foreign commerce. In addition, the RGGI will directly influence U.S. relations with foreign countries, and indirectly undermine current U.S. strategic positions advanced at international fora such as the United Nations and the current Doha Round of WTO negotiations. Arguably, the RGGI also could help to establish the use of the precautionary principle as an exercise of ‘state (regional and ultimately national) practice’, as a matter of binding customary international law, although the U.S. has affirmatively decided *not* to remain a party to the Kyoto Protocol.

Sixth, and most problematic of all, the RGGI *was designed* to be held out as a model to the nation – i.e., to be quickly expanded to other U.S. states and regions and to cover other U.S. carbon dioxide emissions sources. Consequently, RGGI could potentially serve as a template for the enactment of other regionally-based health and environmental regulatory agreements among U.S. states that are modeled after other (non-climate change-related) precautionary-principle-based EU regulations. This could adversely affect a broad array of U.S. agricultural and industrial products. A RGGI clone is already being negotiated on the West Coast between California, Oregon and Washington. It would arguably extend beyond power utilities and automobile manufacturers to include all industrial and commercial sources of carbon dioxide.

C. State and Local Law Initiatives to Adopt the Precautionary Principle

During the past several years, several American states, including Massachusetts, New Hampshire, Hawaii and New Jersey have considered adopting the Precautionary Principle formally as state law. During June 2003, the City of San Francisco became the first city within the United States to actually adopt the precautionary principle as municipal law. During September 2004, the City of Portland, Oregon became the second U.S. municipality to do so. On February 22, 2005, Seattle Mayor Greg Nichols announced his intention to “lead a campaign to get U.S. cities to adopt [the terms of the] precautionary principle-based Kyoto Protocol.”

IX. EFFORTS TO REFORM U.S. FEDERAL LAW

A. State Attorneys General Lawsuits on Climate Change

State Attorneys General have filed several lawsuits during the past few years hoping to move climate change policy from the elected branches to the courts. They commenced these actions precisely because neither the Congress nor the Administration had chosen to address climate change issues in the manner advocated by European leaders and transatlantic environmental groups – i.e., by ratification of the Kyoto Protocol.

The first group of suits challenged the U.S. Environmental Protection Agency’s failure to regulate motor vehicle GHG emissions as ‘air pollutants’ under the federal Clean Air Act (CAA). These actions were brought by twelve states, the District of Columbia, the cities of Baltimore and New York and the island of Samoa. According to at least one legal expert, the suits constituted a back-door attempt “to force federal regulation of carbon dioxide...by piggybacking such controls onto overdue revisions of pollution-control requirements for industrial facilities.” If these suits are successful, this expert believes that it “would have dramatic [legal and economic] implications, as the EPA would be empowered – and in some cases required – to adopt far-reaching restrictions on activities that result in greenhouse gas emissions.” It would also impose significant economic costs on states which rely on coal for energy production or primarily use natural gas or other fuels. This prompted eleven such states to subsequently file an amicus brief in support of the EPA position.

Oral arguments for this highly politicized case took place on April 8, 2005, and the court rendered its decision, in favor of the EPA, on July 15, 2005. The resulting split-decision went as far as to employ a combined and comprehensive standing *and* merits analysis to conclude that the EPA had acted completely within its administrative discretion to reject the petition. However, a loquacious 38-page dissenting opinion suggesting grounds for reversible error and public statements (‘media spin’) made by such activist groups as the Natural Resources Defense Council strongly suggest that the ruling will likely be “appealed by the states or environmentalists either to the entire circuit or even up to the Supreme Court”.

The second group of suits targeted five of the largest U.S. public utility companies in an attempt to curb their greenhouse gas (GHG) emissions. They alleged that the large utilities’ carbon dioxide emitting activities contribute to a ‘public nuisance’ as defined under federal common law. The precedent-setting remedy they seek is not monetary in nature – rather, they have petitioned for the utilities to abate the nuisance they have created by reducing their greenhouse gas emissions.

B. Efforts to Enact Federal Legislation on Climate Change

On February 10, 2005, Senators Joseph Lieberman (D-CT) and John McCain (R-AZ) reintroduced their Climate Stewardship Act of 2005. This bill was nearly identical to the proposal that they had

introduced at the beginning of the 108th Congress, known as the Climate Stewardship Act of 2003. The goal of the CSA was to impose *mandatory and economy-wide emissions reduction requirements* to ensure that U.S. national GHG emissions are reduced to their 2000 levels by 2010 and to 1990 levels by 2016. By contrast, the Kyoto Protocol requires that the U.S. national GHG emissions be reduced to 7 percent below its 1990 emissions by the end of the period spanning 2008-2012. The CSA would have accomplished this by establishing a GHG emissions-trading program similar to the one currently used to control releases of pollutants that cause acid rain. The trading of emissions allowances and reductions would have been made possible by enactment of a National Greenhouse Gas Database containing an inventory of emissions and registry of reductions.

On June 22, 2005, this reworked bill suffered the same fate as its predecessor – it was soundly rejected (pursuant to a vote of 60 to 38) by the U.S. Senate, despite British Prime Minister Tony Blair’s personal appeal to individual senators to more proactively address global warming. However, this bill’s defeat was followed by the adoption of a narrowly approved (54-43) *non-binding* Senate resolution expressing the “Sense of the Senate on Climate Change”, which had, only hours earlier, failed as tabled Amendment No. 866 to the comprehensive energy bill (The Energy Policy Act of 2005 - H.R. 6). H.R. 6 was passed by the Senate 85-12 one week later (on June 29, 2005).

The resolution, a highly charged and self-contradicting statement in its own right, was introduced by Senator Jeff Bingaman (D-NY) and signed by Senators from both political parties, including “Republican Pete Domenici of New Mexico, chairman of the Senate Energy Committee”. It “finds that there is a growing scientific consensus that human activity is a substantial cause of greenhouse gas accumulation in the atmosphere”, and calls for “Congress [to] enact a comprehensive and effective national program of mandatory, market-based limits and incentives on emissions of greenhouse gases...”

On February 15, 2005, Senator Hagel (R-NE), along with three Republican Senate co-sponsors, Lamar Alexander, Larry Craig and Elizabeth Dole, had introduced the Climate Change Comprehensive Legislative Reform Act of 2005. It was comprised of three separate bills, S. 386, S. 387, and S.388 (/883), which addressed respectively international policy, tax policy and domestic policy. The Climate Change Technology Deployment in Developing Countries Act (S.386) in particular, promoted the exportation by U.S. companies of U.S. greenhouse gas intensity reducing technologies and practices to, and their adoption by, developing countries. To promote the diffusion of such technologies (e.g., ‘clean coal technology’) in developing countries without risk of trade reprisals, the U.S. Trade Representative (‘USTR’) would negotiate the removal of trade-related barriers within those countries.

Apparently, many of these bills’ provisions were retained in a subsequent amendment proposed by Senator Hagel and others and later passed and incorporated within H.R. 6 on June 21, 2005. Arguably, if H.R. 6’s climate change provisions survive conference and are passed by both the Senate and the House without much modification, it would likely extinguish any constitutional claim that states, individually or regionally, could conceivably make to justify their regulation of greenhouse gas emissions generated by autos and power plants operating within their jurisdictions.

Despite the voluntary nature of the GHG reductions called for in the bill, however, U.S. companies would expect to use any project-related GHG ‘offsets’ under the EU ETS or any future U.S. federal or regional (e.g., RGGI) climate change regime. This could, in effect, raise significant market-related and economic/financial costs for certain companies. It is arguable, for instance, that any GHG registry, even if voluntary, might trigger a domino effect that could generate the type of arbitrary and artificial discrimination between and distinctions among U.S. companies and their products and services which the U.S. has objected to, as a matter of international trade law, at the WTO. While the proposed GHG emissions registry may be intended to promote only *voluntary* company reporting of GHG emissions and credits for purposes of future use *in the event* a mandatory emissions trading cap were ever imposed, it is likely to have the same practical effect.

The energy conservation, income tax incentives and domestic public-private partnership research and technology development provisions of S.387 and the joint international research and technology development provisions of the previously unveiled (2002) Bush Administration Climate Change Plan would be much preferred. These proposals would more likely provide U.S. industry with the ability to achieve the substantial technological breakthroughs needed and the environmental benefits desired at a lower economic and social cost overall to American society; i.e., without jeopardizing the American free market enterprise and legal systems and the American comparative advantage in international trade in the process. Based on the provisions of H.R.6, a number of senators agree.

C. Efforts to Change Environmental Accounting and SEC Disclosure Rules (Non-SOX)

In a paper released during 2001, an EPA official accused U.S. public companies of not adequately complying with their obligations under U.S. federal securities laws to disclose environmental performance information demanded by equity investors such as social investment funds and environmental groups. The paper contended that such noncompliance translated into an “information asymmetry market failure,” and that as a result, “[i]nvestors and fund managers that want to take advantage of the link between environmental and financial performance to use corporate environmental performance as a criteria for selecting or screening stocks are at a disadvantage...”

The financial disclosure requirements to which the EPA official referred are contained within three different sections of Securities and Exchange Commission (SEC) Regulation S-K. The most indeterminate of these provisions is S-K 303, which generally addresses the costs of *future* environmental risks. It requires companies to discuss their liquidity, capital resources and results of operations. It also requires the company to identify *any known trends*, demands, commitments, events, or *uncertainties* that may result (or be ‘reasonably likely to’ result) in a ‘material’ change (favorable or unfavorable) in the company’s net sales, revenues or income from continuing operations that may not otherwise be reflected in the financials. This part of the filing is known as ‘*Management’s Discussion and Analysis of Financial Condition and Results of Operation*’ (*MD&A*). It is within this non-financial section that the SEC would expect to see management’s evaluation of the potential material effects of known trends (evolving foreign regulatory trends) and uncertainties (environmental contingencies) on company financial operations or capital resources.

Beyond the S-K Regulation disclosure requirements, the SEC relies also on the professional standards and guidance documents issued by the Financial Accounting Standards Board (FASB) and the Public Company Accounting Oversight Board (PCAOB). Such standards and guidance documents help to ensure that companies are properly accounting for and reporting on their financial operations, including any environmental losses resulting from liabilities from permanent reductions in the value of company assets. The SEC presumes that financial statements not prepared in accordance with generally accepted accounting principles (GAAP) promulgated by the FASB are misleading and inaccurate.

During August and September 2002, the Rose Foundation for Communities and the Environment, an environmental and corporate accountability activist group, filed with the SEC a rule change petition (#4-463). That petition requested that the SEC “promulgate two new rules “to clarify the intent of the Commission’s material disclosure requirements with respect to *financially significant environmental liabilities* and to help ensure compliance with existing material financial disclosure requirements” (emphasis added). The proposed mandatory rules, which are a departure from current GAAP requirements, would be based on two voluntary, but not widely adopted U.S. industry standards. The filing of this petition evidenced a back-door attempt by risk-averse social and environmental activists to hold public companies financially accountable for uncertain future health and environmental hazards (e.g., climate change), even if they have not yet been addressed in legislation or regulations.

During October 2002, Senators Jeffords (I-VT), Lieberman (D-CT) and Corzine (D-NJ) requested that the U.S. Congress General Accountability Office (GAO) prepare a report on SEC corporate environmental disclosure regulations, their implementation by the SEC, and companies' compliance therewith. In particular, the members requested that the GAO analyze the perceived 'gap' that exists between what companies actually report to shareholders and what markets, analysts and insurers believe is the potential real liability of environmental costs and risks. During April 2003, the United Nations Commission for Environmental Cooperation of North America and the United Nations Environment Program Finance Initiative (UNEPFI) issued a report evaluating why the mainstream U.S. financial community had not been demanding environmental information from public companies. Coincidentally, it focused on the nondisclosure of environmental issues by companies in the mining, manufacturing, chemical, building, petroleum, pulp and paper, and insurance sectors.

During November 2003, the Treasurers from the States of California, Connecticut, Maine, New Mexico, Oregon and Vermont, and the Comptrollers of the State and City of New York, and two leading Labor Pension Funds submitted a '10 point call for action' to the SEC. It called upon the SEC "to enforce corporate disclosure requirements under regulation S-K on material risks such as climate change and to strengthen current disclosure requirements — as requested by investors and others in petition # 4-463."

During July 2004, the GAO issued its report. In general, it found that current disclosure of environmental information was not inadequate. In addition, it determined that without more compelling evidence that the disclosure of environmental information is inadequate the need for changes to existing disclosure requirements and guidance or increased monitoring and enforcement by SEC is unclear. Furthermore, the GAO recommended that the SEC cooperate and regularly exchange information with the EPA. Unconvinced by the GAO's findings, the activist Rose Foundation released another report later that month, once again raising the bar on corporate disclosures. It argued that emerging scientific concerns about potential health and environmental hazards that are reflected in peer reviewed scientific journals are subject to disclosure under SEC rules, whether or not they may 'materially' affect a company's operations or finances.

D. Efforts to Reform Federal Food, Drug and Chemicals Regulations

1. Agricultural Biotech/USDA/FDA/EPA

As the result of the biotech industry's rapid expansion beyond basic biotech products, the competitive concerns of a growing U.S. organic food industry and the intense political pressures generated by the EU Commission and ENGOs, the current U.S. biotechnology regulatory framework which addresses potential 'risks' as opposed to hazards is now once again under review. According to U.S. media reports, some groups want Congress to pass a new biotech law that would more adequately review the potential health and environmental impacts of the newest generation of biotech products. These groups believe that America should adopt Europe's skepticism toward biotech crops and the ability of the current patchwork of a "U.S. regulatory system to [manage] such technology. They seek for the U.S. to return to the prior 'Delaney Clause' era now embraced by Europe.

2. FDA/Medical Biotech

Some commentators believe that the current clamor for biotech regulatory reform may be tied to the current controversy over certain pharmaceutical drugs which were initially approved by regulators as safe but later alleged to be harmful to some patients. This has led to the introduction of bipartisan federal legislation calling for drug companies to make clinical trial information more transparent and publicly available to both ensure drug safety and maintain consumer confidence. Financial analysts are divided

over whether the current demand for more safety-oriented reform at the FDA will cause regulators to buckle under the pressure and to reintroduce a precaution/ hazard-based evaluation approach that would also subsume the biotech sector.

3. *FDA/Antimicrobial Animal Drugs*

Since 1997, the EU has banned a class of five ‘growth-promoting antibiotics’ administered in animal feed on the basis of the precautionary principle due to concerns that microbial-resistant bacteria will possibly travel from the food products of slaughtered animals to the humans who consume them. The EU bans, none of which were based on the results of a scientific risk assessment, have “had adverse consequences for animal health and welfare” and farmers have suffered significant economic losses from reduced animal production. Mounting political pressure from European and American ‘consumer’ groups, however, have since caused the FDA to issue during October 23, 2003, a new review procedure intended to address the risk of anti-microbial resistance. Industry Guidance Document #152 set forth non-binding recommendations “for assessing the safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern”, which the FDA intends to follow. Some commentators believe that this document reflects hazard/precaution -‘creep’, given its focus on hazard characteristics, its minimization of *quantitative* risk assessment and its disregard for economic cost-benefit analysis.

4. *Toxic Chemicals/EPA*

Ideological environmental groups have launched significant public pressure campaigns against the EPA’s voluntary High Production Volume (‘HPV’) Challenge Program, calling it inadequate and unequal to the task of publicly identifying the *potentially hazardous properties and uses* of more than 30,000 existing chemicals being commercially traded within the U.S. These groups have also pressured the EU Commission to revise its proposed REACH high volume chemicals regulation so that it is once again more stringent. As a result, the U.S. EPA HPV program seems to have taken on new life during the past year, with ideological environmental and animal welfare groups being granted a growing and influential role in this program.

In addition, the EPA’s National Pollution Prevention and Toxics Advisory Committee (NPPTAC) has asked its HPV Challenge Program Work Group “to develop and propose a *hazard-based screening process* to organize the chemicals in the submissions received...[to] guide their further review by OPPT” (emphasis added). Remarkably, this seems to negate the very public policy position taken by the U.S. government and by the U.S. chemical industry against the extraterritorial impact of the proposed EU REACH regime. As in the case of the EU REACH regime, companies are required to undertake a risk assessment of specific chemicals only *after* a chemical has already been characterized, categorized and ultimately stigmatized as *hazardous* and subject to disclosure in an electronic public database.

And, these efforts have recently come to fruition. On July 13, 2005, the Government Accountability Office (GAO) released what is certain to become a politically-charged report that is entitled, “Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program”. It was prepared in response to inquiries previously made by three prominent senate proponents of the precautionary principle – Senators James M. Jeffords (I-VT), Frank R. Lautenberg (D-NJ), and Patrick Leahy (D-VT). The report claims to have evaluated EPA’s ability “to (1) control the risks of new chemicals not yet in commerce, (2) [to] assess existing chemicals used in commerce, and (3) [to obtain more] publicly disclose[able] information [from] chemical companies under TSCA.

Predictably, the report concludes that the EPA lacks the ability under current federal statutes (e.g., TSCA and FIFRA) to assure that health and environmental risks are identified before the chemicals enter the stream of commerce. It then sets forth a list of recommendations that focus on ways to revise those

statutes to provide the EPA with such ability. For this purpose, the report contains multiple references to the precautionary principle and hazard-based EU REACH regulation which imposes a zero-risk threshold and eschews economic cost-benefit analysis. If adopted, these recommendations would essentially end the statutory case-by-case testing approach now employed under federal law, and establish an across-the-board pre-market precautionary principle-based testing regime as the *de facto* regulatory framework standard for evaluating chemicals (and perhaps other substances and products) within the United States.

Considering how the role of quantitative risk assessment based on exposure has been minimized, one is led to wonder how much objective science is actually being employed, even if industry-favored SIDS (Screening Information Data Set) endpoints are utilized. And what would the result be if non-SIDS endpoints were incorporated into such a screen? While there may be complexities and technical differences that separate the EPA's HPV Challenge Program from the EU's REACH, they are not as stark as they once were. To the extent U.S. industry support for the EPA's HPV program results in a domestic U.S. government policy position that is inconsistent with its international policy position against the EU REACH, it will only work against the U.S. chemical and downstream industries in the longer term. As the scientific benchmark standard for evaluation and disclosure of public risks (exposure-based quantitative risk assessment) is progressively minimized and 'watered down' by subjective non-science-based hazard characteristics and EU-like reinterpretations of OECD endpoint criteria, it will become increasingly difficult to prevent the return of Delaney Clause-era pre-market regulatory authorization and legislation.

5. *Waste Disposal and Take-Back/EPA*

During 2003, Representative Mike Thompson (D-CA) introduced a bill within Congress that, like analogous European regulations, would mandate and finance waste disposal and recovery/ recycling at the federal level - The National Computer Recycling Act (H.R. 1165). Although this bill was never acted upon, it was recently reintroduced by Representatives Thompson and Louise Slaughter, (D-N.Y.) as H.R. 425, during January 2005. These bills reflect environmental group concerns that "toxic substances in e-waste could possibly harm human health and the environment, even though there is no scientific evidence that toxic substances leach from e-waste when it is placed in landfills."

During January 2005, Representatives Randy Cunningham (R-CA) and Eric Cantor (R-VA) introduced waste recycling-related legislation (H.R. 320), which has since been referred to the House Ways and Means Committee. Unlike the regulatory-centric bill noted above, this bill sought to encourage the recycling of e-waste by businesses by granting "tax credits [incentives] to manufacturers who recycle electronic equipment...[computers cell phones and television equipment]...in an environmentally sound and responsible manner."

X. IMPOSING PRECAUTIONARY PRINCIPLE-BASED SUPPLY CHAIN MANAGEMENT STANDARDS – THE GROWTH OF 'SOFT' LAW

A. General

Whether U.S. small and medium-sized businesses export their U.S. manufactures to Europe, source and import their products from China, or are engaged exclusively in a domestic business, they are all likely to be affected by global supply chain management programs. These programs, which incorporate the precautionary principle, are being promoted by the EU Commission and prominent international environmental, corporate governance and corporate social responsibility groups.

B. The EU and the United Nations as Protagonists

During the past three-five years, the UN Global Compact Office and the UN Environment Program (UNEP), with the support of the EU Commission and EU Member States, have convened several public-private partnership meetings and global business dialogues that have focused on the issue of global supply chain management. An overarching theme within these ostensibly ‘voluntary’ initiatives has been the promotion of *global* corporate social responsibility (CSR) standards that require companies, wherever they operate, to adopt at least a ‘precautionary approach’ (effectively, the ‘wingspread’ version of the precautionary principle) to environmental challenges in all product and service sectors. The corporate social responsibility work of the Global Compact Office and the environmental work of UNEP are further supported by the activities of the U.N. Commission on Sustainable Development (CSD), which organized the 2002 World Summit on Sustainable Development (WSSD). The CSD reports to the U.N. Economic and Social Council (ECOSOC), which functions under the authority of the U.N. General Assembly.

While environmental NGOs are at the forefront of these initiatives, the EU and the United Nations are the catharsis behind them. Indeed, they continue to encourage ENGOs to employ pressure tactics against public-image sensitive U.S. multinational corporations in order to reach their small and medium-sized suppliers. A recent paper prepared by the Chief of the UN Treaty Section explains and justifies the increasingly popular strategy of employing ‘name and shame’ or public disparagement campaigns to this end.

Environmental and labor groups have continued to utilize global supply chain management to publicly compel U.S.-based multinationals commanding significant U.S. and international market share to adopt EU precautionary principle-based labor, social and environmental (CSR) standards. Some of the best known examples of this program involve the retail buying groups formed among large European and U.S. supermarket chains, office supply retailers and home-improvement retailers and mass and discount clothing manufacturer/retailers. More recently, ENGO campaigns have focused on prominent U.S.-based international commercial and investment banks.

Since its inception, the U.N. Global Compact Office’s primary mission has been to convince U.S. companies of the moral, social and environmental virtues of developing broader and more transparent internal governance systems, in line with evolving ‘international’ (mostly European) CSR standards that support sustainable development. It has also endeavored to link CSR performance with financial performance by hypothesizing about how the regular flagging of EHS issues to corporate directors and executives and the detailed and accurate public reporting and disclosure of both financial and non-financial EHS-related items, can enable companies to achieve qualitatively better corporate governance, improved brand reputation and enhanced shareholder value.

However, the links between corporate EHS and financial performance that the U.N. and ‘first-mover’ companies (Global Compact participants) seek to prove are difficult to draw, as they are extremely subjective and fact-intensive. It may be true that “[i]ntangibles such as R&D, proprietary intellectual property and workforce skills, world-class supply networks and **brands** are now the key drivers of wealth production. It may also be true that U.S. and international accounting rules concerning ascertainable intangibles acquired in a business combination, including goodwill and product/service brands, have been revised to require annual ‘marked-to-market’ valuation, which engenders greater asset, income, and hence, stock volatility. Nevertheless, companies remain hard-pressed to establish corporate EHS performance as an independent asset susceptible to valuation. This leaves only the deep-seeded social investor, civil society and global stakeholder notion that “business fundamentals [should] go beyond audited financials”, and the positivist /utopian view of the social and philosophical role that accounting information *should* serve in an increasingly shared and interconnected global community, as the basis for CSR – hardly a fulfilling proposition.

XI. THE BROADER INTERNATIONAL LEGAL, POLITICAL AND ECONOMIC IMPLICATIONS

A. The Legal Rights of Individuals vs. the Collective Legal Rights of Society

Some American and European academics have concluded that the different approaches employed by Europe and the U.S. to address food safety (and arguably environmental) risks (a *hazard* assessment ex-ante *regulatory* approach vs. a *risk* assessment ex-post market *legal* approach) are attributable to fundamental underlying constitutional differences between these two regions. These constitutional differences, in turn, reflect different notions as concerns the rights of individuals versus those of society, of the role of government in balancing between those rights and of the relative functions served by the different institutions of government.

B. EU Cultural Values Are Critical of U.S. Free Markets – The Role of Social Welfare Theory

Reading between the lines, it is obvious that Europe's goal of establishing the precautionary principle first, as a regional regulatory framework, and then, as an absolute global legal standard, actually represents a much broader political and social agenda. In effect, it is to impose on the U.S. and all other nations *its* regional value system vis-à-vis a disguised global social wealth redistribution scheme. The EU's scheme is critical of and aspires to compete with free market capitalism. These *regional* values are clearly embodied within the social welfare doctrine of 'sustainable development' that the European Commission and European civil society groups have tirelessly promoted as a new *global* 'development' paradigm at the United Nations.

The EU has arguably utilized this concept as a reason for calling on World Trade Organization (WTO) member governments to support changes to the international legal benchmarks they currently rely on to evaluate the safety or harmfulness of everyday products, processes and activities. Europeans believe that such changes are possible so long as they can establish the precautionary principle as an absolute international and U.S. legal standard. If they are successful, the role of science and economics in assessing and managing global public risks would be severely undermined. This, in turn, would effectively slow down U.S. technological innovation and economic progress and thereby threaten American industries' entrepreneurial spirit and global competitiveness.

C. Exporting Social Welfare Statism to Constrain U.S. Industry – Securing a Competitive Economic Advantage

At the global level, Europe's vision of a utopian society also has a pragmatic dark side – Europe's need to maintain its global economic competitiveness by avoiding what some academics have referred to as a 'prisoner's dilemma'. Europe's penchant for *over*-regulation and its embrace of 'enhanced welfare state' economics have arguably rendered it unable to close its economic growth gap with North America and Asia, and likely explains why Europe has fallen behind in its public quest to surpass U.S. economic competitiveness by 2010. Europe, therefore, has no choice but to export its high cost precaution-based regulatory framework abroad in order to shift a portion of the economic burden (hence the familiar term 'burden sharing') to other countries, especially the United States. It is believed that this will serve to slow down American technological and economic progress enough, at least, for European industry to regain its international competitiveness.

At least one legal expert has observed that Europe's exportation of protectionism under the guise of strict health and environmental regulation is a hallmark of the trading bloc mentality that characterizes the new global economy of mercantilism. The World Bank referred to this practice within one of its recent reports. Its findings reflect that European industry has worked alongside the EU Commission and European environmental groups (i.e., there was a convergence of interests) to adopt a region-wide precaution-based import ban against American, Canadian and Argentine GM food, feed, and seed exports. This is not, however, the only World Bank report that has addressed the extra-territorial burdens imposed by European precaution-based *food* regulations and product standards. In fact, there are a number of others. Together they reveal a troubling pattern – namely, that protectionist motivations also underlie many other EU *nonfood*-related regulations and technical standards, such as those relating to wood-based forest products, chemicals and downstream products, and manufacturing activities and products deemed to cause air pollution and climate change. And, as precautionary principle advocates have explained, this *economic* rationale is actually historically based.

D. Using European Cultural Values to Change International Law

Despite its apparent political appeal, Europe's practice of erecting disguised technical trade barriers cast in the form of stringent precautionary principle-based EHS regulations and product standards, however, runs counter to both the letter and the spirit of at least three World Trade Organization Agreements. Such a practice has often resulted in unfair discrimination between otherwise identical or similar products based on political preferences for particular production processes. In other cases, it has resulted in the creation of unnecessary obstacles to international trade flows that could have been avoided had other available, less trade-restrictive, alternatives been utilized.

The only WTO legal provision that has been interpreted as providing WTO Members with the right to apply a *precautionary approach* is Article 5.7 of the SPS Agreement, which covers technical regulations and product standards addressing *food safety* issues. However, it must be emphasized that this is a provisional exception of limited duration that can be invoked by governments only in the case of scientific uncertainty, i.e., where an objective science-based risk assessment has failed to provide sufficient evidence of a significant human or plant health risk, though one is nevertheless believed to exist.

Well aware of the limited duration of such an exception and the difficulty of satisfying these tests, the EU Commission and precautionary principle advocates have sought to establish the precautionary approach as a more formal and expansive *precautionary principle* (i.e., as a general norm of customary international law) that transcends the WTO Agreements to guarantee "its adoption, implementation and diffusion" in other countries. By exporting the precautionary principle throughout the world in this manner, many scholars argue that the EU can help to formulate new customary international law that would need to be considered during the course of a WTO dispute involving national or regional precaution-based health and environmental regulations and standards. However, other scholars disagree.

Were the EU able to establish the precautionary principle as a norm of customary international law, it raises the prospect that U.S. federal court jurisdiction may ultimately be invoked successfully under the provisions of the Alien Torts Claim Act ('ATCA') to hear health or environmental claims brought by foreign nationals injured in their country. In light of the U.S. Supreme Court's recent ruling in the *Sosa* case, this should no longer be considered a remote possibility. In addition, the precautionary principle could also be construed by the U.S. Supreme Court, and thus by lower federal courts, as equivalent to federal common law, as an increasing number of legal scholars believe it should be. In either instance, the precautionary principle may be held to bind U.S. regulators and American companies, even though the U.S. government has chosen not to ratify precaution-based environmental treaties.

XII. CONCLUSION

In sum, the U.S. business community as a whole should not fail to explore all conceivable and available options, opportunities and vehicles that could potentially help it to extinguish the complex challenge posed by the precautionary principle. At this juncture, it is not an overstatement to say that the stakes are enormous. America's very enterprise system, individual freedoms and international interests – its core political and economic values -- are hanging in the balance. Transatlantic regulatory and parliamentary dialogues, diplomatic confidence-building initiatives, and EU integration and constitution empathies aside, we must immediately come together *as Americans* and collaborate in order to halt Europe's misguided global regulatory juggernaut before it is too late!

This paper will form the basis for a forthcoming Washington Legal Foundation Monograph, to be released by the Foundation's Legal Studies Division in August 2005.