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SOME LEGAL IMPLICATIONS OF THE PRECAUTIONARY PRINCIPLE: IMPROVING INFORMATION-GENERATION AND LEGAL PROTECTIONS

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Abstract. In creating a legal agenda in service of the Precautionary Principle, the idea of precaution requires more inventories and better monitoring of the condition of public and workforce health than at present. Rectifying problems of the past to better serve the aims of precaution will require more affirmative pre-market and much more post-market knowledge-generation by those who create and use potentially toxic substances, improved pre-market review of substances, better responses to early warnings, and quicker protective post-market responses to evidence of toxicity. This paper conceptualizes a model pre-market screening law to highlight the need for primary prevention measures and to provide philosophic ideas for improving post-market laws and addressing a large universe of existing substances that have been poorly characterized. Although retrospective personal injury law does not have good mechanisms for precaution, even this can be more protective than it is at present by enhancing causes of action for reasonable fear of disease and medical monitoring, and moving to create new causes of action for failure to develop and disseminate information needed to assess the toxicity of substances.

Key words:
Precautionary Principle, Pre-market laws, Post-market laws, Expedited procedures, Knowledge-generation

INTRODUCTION

Creating a legal agenda for precautionary approaches to workplace and environmental health protections rests on a conception of what precaution requires, diagnoses of past problems, legal devices for addressing the problems, and how some strategies might remedy past problems and create conditions for better primary prevention from harm in the future. Such an approach is especially important as we enter an era that will introduce new technologies, such as biotechnology and nanotechnology. The discussion that follows addresses these issues by conceptualizing a model pre-market law, drawing on some attractive features of existing pre-market US laws, to provide ideas to guide precautionary legal strategies and to serve as a foil for assessing other legal approaches. The paper's aim is philosophical rather than a critique of any existing legal system or parts thereof. Once some obvious strategies become clear, the shortcomings of and improvements on many current post-market laws become manifest. The suggestions that follow are not a complete analysis, only *prima facie* recommendations following the spirit of primary prevention of harms and significant risks. No doubt there would need to be some modifications for full implementation.

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THE IDEA OF PRECAUTION

This analysis begins with the concept of precaution instead of a particular formulation of the Precautionary Principle (PP). The idea of precaution tends to be broader and to reveal more of the implications of precaution. There are also sufficiently numerous formulations of PP that make it difficult to know which, if any, might be regarded as canonical (although the United Nations (UN) principle is one place to begin).

Implicit in the idea of precaution is a view about the value or importance of a thing or state of affairs toward which one might take precaution and exercise precautionary actions. Something that is of great value to us is threatened and merits preventive and protective action in order to avoid threats to it or to prevent any threats from materializing into harm. It might be highly valued people or things around us, e.g., children or other loved ones, or precious art objects, for example, such as Michelangelo's Last Judgement. Because we value them highly, we exercise foresight, *Vörsorgeprinzip*, in planning our activities toward them [1]. A more thoroughgoing ideal of precaution would be to take anticipatory and planning steps to consider alternatives in arranging our activities in order to avoid threats to the integrity or well being of things we care about and to prevent existing threats from materializing into harm [2]. For example, the managers of the Sistine Chapel do not wait to see whether smoking will pose a threat of serious or irreversible damage to the Last Judgement before they decide that smoking simply will not be permitted; they know enough to avoid such threats in the first place.

The concept of precaution also suggests that one exercise foresight and planning toward some valued thing or state of affairs that has already been damaged both in order to prevent further deterioration and to assist in restoring it to some desirable condition, e.g., soccer players take precautions toward their knee injuries to prevent further damage and to restore their function so that the players can continue to compete at some high level.

Formulations of the PP presuppose the unique or high value of various environmental resources and the importance of protecting human health, or, conversely, a view about the terrible or degraded condition of some aspect of the environment or human health that is highly valued. On the one hand, for example, some areas of the earth and human health appear to be so threatened by the presence of polychlorinated biphenyls (PCBs) that are far from their sources [3] that decision makers should utilize planning and foresight in order to prevent further damage from them, and, if possible, to restore the environment and human health to some desirable *status quo*. Much more recently discovered toxicants, such as polybrominated diphenyl ethers, structurally similar to PCBs [4], bromopropanes [5], and some phthalates [6], raise new concerns. On the other hand, for example, the rain forests of the world may be so threatened that the PP would urge that decision makers have the foresight to protect them to ensure that threats do not arise or, if they do, that the threats not materialize into harm. Other environments have been damaged and a precautionary approach would suggest that the damage should be rectified with the aim of restoring them to a previous valued *status quo*, e.g., comparatively pristine air, water, oceans, and wilderness are disappearing, freshwater sources are limited, cropland is shrinking, worldwide fisheries are depleted, species are disappearing, and human activities are causing global warming and the ozone hole [1,7–9].

A PARTIAL DIAGNOSIS OF PAST PROBLEMS

Some environmental and workplace health problems have arisen because of actual harms caused; other potential problems exist because of various informational deficiencies, while still others resulted from delayed responses to problems or legal strategies that frustrated or slowed precautionary protective responses. Different legal strategies are needed to address different problems.

High profile harms to health and the environment

Various high profile harms to human health and the environment have been well documented. These include, for example, health and environmental damage done by DDT, chlorofluorocarbons, PCBs, lead, mercury, cadmium,

nickel, benzene, asbestos, and other toxicants, as well as poor disposal practices.

Lack of knowledge about the effects of human actions on workplace and public health. Beyond actual harm, there is considerable ignorance about the effects of humanly created chemical substances on the environment and on public and workplace health. These problems have a number of facets that precautionary approaches should address.

Little monitoring/surveying of the current state of the environment and public health. If there are substantial deficiencies in what we know about the cumulative effects of human activities on the environment and on human health, the idea of precaution would require that we remove this ignorance. Some monitoring has been done, but it appears that much more could be done to survey the *status quo* to understand the condition of the environment, as well as the public and workforce health [10].

Ignorance of the universe of potentially toxic substances. There are about 20 500 000 unique organic and inorganic chemicals. There are about 100 000 substances or their derivatives registered for commerce and in common use in the US [11]. Of these about one-third present little or no exposure and perhaps another 23% are polymers, thus likely presenting at worst only minimal risks [12]. There are another 800–1000 added to the list each year with no legally required testing [13]. Although there is little testing of substances other than those explicitly subject to pre-market screening laws, firms have good reasons to conduct short-term tests and use structure-activity information to prevent obvious toxicants from entering commerce, producing some congruence between a firm's private interest in being safe rather than sorry later and the public interest in health protections. Nonetheless, the US Congress' Office of Technology Assessment found that some substances approved for manufacturing under pre-market notification laws (that do not require testing) have "demonstrated toxicity" [13].

Scientists appear to know little about this universe of 100 000 substances. In 1984, the US National Academy of Sciences found that there were 12 860 substances produced in volumes exceeding one million pounds per year for 78% of which there is *no* toxicity information available, 13 911 chemicals produced in volumes of less than 1 million pounds (76% with no toxicity data), 8627 food additives (46% with no toxicity data), 1815 drugs (25% with no toxicity data), 3410 cosmetics (56% with no toxicity data), and 3350 pesticides (36% with no toxicity data). In the early 1990s there was insufficient change in the data to justify updating the National Academy Report [14,15]. Of a group of 3000 substances produced in the highest volume, there remained substantial knowledge gaps for about 75% of them as recently as 1998, when the US Environmental Protection Agency (EPA) entered into an agreement with the producers to close the knowledge gaps [16]. These were likely the most worrisome of the high-production volume substances, but as late as 1995 the US Congress, Office of Technology Assessment found that there are another 1000–12 000 for which extensive toxicological information would be quite important but which is not available [17].

It thus appears that free enterprise institutions have created and distributed thousands of substances, without substantial information about their effects on human health and the environment, other than minimal testing done out of self-interest. In effect these substances and knowledge about them appear not well controlled by the institutions that could protect public health and the environment. Any primary prevention from harm from these substances that could be provided by legal institutions tends to be undermined by extensive ignorance about them. Moreover, some firms themselves have added to the problem by deliberately keeping information from agencies or falsifying data, etc. [18].

This generic concern is manifested in several more specific ways. In the current economic system there are asymmetries in what is known about the benefits and risks of products: companies conduct considerable research on the benefits of products, but appear to investigate much less the potential adverse consequences of their use, distribution and disposal. Moreover, more than minimal testing for adverse health effects appears not to be contemporaneous with the production of products or as thorough as

research into their beneficial features. A good corporate citizen would conscientiously investigate potential adverse effects as well, but good corporate citizens may not be common as recent events in the US financial markets have suggested.

Moreover, long-term effects are even less well known than short-term adverse effects. When there is a short lag time between environmental or human exposure to a substance and manifestation of adverse effects, it is much easier to detect any causal consequences than when there are longer latency periods for adverse effects. Thus, it is reasonable to suppose that longer-term effects will be even more difficult to detect and that less will be known about them. Firms appear not to compile information about long-term effects and others may not do so either; someone should have a stake in this.

A related point is that there appears to be little or no understanding of the life cycle of products. A company's interest in its products tends to cease once they are sold and warranties have expired, except for the possibility of litigation and the concerns of especially conscientious and far-sighted firms. It is only recently in the US that any firms are attending to the toxic metals in electronic equipment (Hewlett Packard is reportedly beginning a recycling program for computers), although the European Community may have a better record on this. Disposal of used cell phones seems to be a new manifestation of this problem [19]. Similarly, there appears to be little or no understanding of the life-cycle consequences of developing products based upon substances such as lead, cadmium, mercury, nickel, etc. Yet these are likely to pose problems, unless the metals are explicitly recycled or disposed of so that they do not pose health and environmental problems [20]. What other substances in our products may have similar long-term and unexpected life-cycle problems?

It appears that firms are creating their products largely without extensive knowledge of adverse effects and leaving their disposal to the vagaries of happenstance or the market. There has been enough experience with such long-term effects that it is reasonable to expect that such life-cycle analysis would be part of an agenda for the Precautionary Principle and for conscientious corporate citizens.

Lack of information about credible threats of harm. There appear to be few systematic procedures, at least in the US, to obtain information about credible threats of harm from substances. There are some reporting requirements as part of the Food, Drug and Cosmetic Act, (requiring reports on adverse drug and vaccine reactions), the Toxic Substances Control Act, and the Occupational Safety and Health Act (requiring medical record-keeping and reporting of toxicity effects), for example. And, there may be a few other such requirements, but the efforts appear insufficient to provide a systematic picture. It is, thus, a reasonable conjecture that there are inadequate institutional procedures for acquiring information about credible threats of harm to human health and the environment, irrespective of protective responses to credible warnings – that is an additional problem.

Even when there is a reporting requirement to provide information about credible threats of harm, except for pharmaceuticals, not many chemicals are required to be tested.

Asymmetries in scientific methodologies tend to protect against false positives compared with false negatives and reinforce post-market statutes. Many of the asymmetries just summarized are exacerbated by the norms of scientific epistemology. Scientific research tends to be data- and labour-intensive, as well as more concerned with preventing false positive results from studies and inferences than with preventing false negatives (the object of precautionary action and primary prevention of harm) [21]. Thus, it will be difficult or impossible to close these knowledge gaps in any expeditious manner. If a centralized agency such as a government must do it, it will likely be even slower. Consequently, in the race to understand and control the universe of substances, the scientific and regulatory communities start way behind and are greatly handicapped by lack of resources, the slow pace of scientific data generation, conventions of scientific epistemology, and the typical legal requirements of many countries. And, given the open-endedness of science, there is always the temptation to demand more and better evidence before drawing

a conclusion with respect to adverse effects [22]. Such epistemic asymmetries pose problems in both pre-market and post- market legal contexts, but they are particularly acute in post-market or personal injury law circumstances in which a scientific case must be established to show harm or risk of harm from exposures before a legal remedy to reduce or prevent harm is permitted.

Slow or absent protective legal responses

Little sensitivity to and/or response to credible warnings of serious adverse effects. In Late Lessons from Early Warnings, the European Environment Agency notes that in the past there have often been credible early warnings of adverse effects on human health or the environment that went unheeded; there were no (or slow) legal or other social responses [20]. This suggests two problems: countries should have in effect some better system for noting credible, early evidence of adverse effects on human health or the environment and have quicker means to provide protection when there are early warnings.

Slow post-market responses. Most of the problems described above are exacerbated to the extent that the toxicity or risks of toxicity from substances must be addressed in a post-market context. Post-market statutes provide for regulation of substances after they are in commerce and people exposed to them, usually with little or no testing, and remain in commerce causing whatever harm they may cause until: 1) there is sufficient scientific evidence (that usually must be initiated or generated by an agency) for an agency to make a case for harms or risks of harm, 2) there is sufficient political will to follow where the science leads, 3) imposed scientific and regulatory standards of proof have become overcome, 4) the regulatory process has been completed, and 5) any legal appeals have been exhausted. Such responses take considerable time in the US and it is a reasonable conjecture that slow responses will only be exacerbated in the future [1,23]. Moreover, under post-market statutes there are numerous structural incentives for firms to resist information-generation about their products, and of course, to resist actual regulation (discussed below). A precautionary legal agenda must address these issues.

In the US these tendencies have been exacerbated by restrictive court decisions that could easily have been decided differently. Several courts, following the lead of the Supreme Court in Industrial Union Department, AFL-CIO v. American Petroleum Institute (the Benzene case concerning more stringent workplace standards for the carcinogen benzene), have placed constraints on protective features of statutes by requiring much more science-intensive support and greater documentation for regulations aimed at preventing workplace and environmental exposures to toxic substances [24]. Appellate courts struck down or made it more difficult for regulatory agencies to issue preventive regulations for exposure to 428 air toxicants in the workplace [25], to prohibit the "future manufacture, importation, processing and distribution of asbestos" in almost all products in the US [26], and threatened the regulation of particulates and other air contaminants [27]. A district court even struck down a risk assessment done on the health effects of exposure to passive smoking by the US EPA, expressing skepticism about whether secondhand tobacco smoke is a human carcinogen, the EPA's selection of epidemiological studies, its use of 90% confidence intervals and the relative risk that provided the basis of concern [28]. Not all appellate decisions have struck down or erected barriers to regulatory actions, of course, but in general in recent years the courts have not been strongly supportive of health-protective regulations.

Court-imposed scientific and regulatory requirements necessitate more studies, increased time for regulation, more documentation of regulations before they are issued, and greater costs. Cumulatively these have two adverse effects on precautionary actions toward workplace and public health: they slow regulation, leaving in commerce the toxicants under consideration and the public exposed to them, and they impose opportunity costs-preventing protective action on other toxicants and exposures [22,29]. Post-market statutes need not be so slow and science-intensive, but post-market regulations tend functionally to create institutional incentives for firms to resist information generation and regulation, and, thus, be data-intensive and slow.

In the tort, or personal injury law, many of the problems are similar, but exacerbated. In torts the primary concern is not to issue regulations to prevent harm from occurring, but to provide post-injury compensation to victims in order to restore them to the *status quo ante* – to make them whole (to the extent that this is possible). Of course, retrospective tort actions do not have explicit preventive or precautionary provisions. However, there can be some indirect preventive effects from the mere presence of the tort law causes of action (depending upon their effectiveness) (general deterrence) or from tort law decisions for plaintiffs that serve as examples to others (deterrence by example). Thus, any precautionary effects are indirect, unless some further causes of action are developed (more on this below) [29].

Judicial decisions in toxic tort law since the leading US Supreme Court decisions in this area – Daubert v. Merrell Dow Pharmaceutical [30] and its sequelae [31–33] – have followed a pattern similar to that set in the Benzene case: federal judges have too often overreacted to a heightened duty to review scientific experts and the basis of their testimony in tort cases and demanded excessive evidence before a tort case can proceed, thus dismissing tort cases for mistaken reasons [34]. This implementation of the Supreme Court cases decreases the accuracy and justice of tort law decisions, increases procedural barriers to those seeking redress for injuries they have suffered and reduces access to the law [29]. The net effects are to decrease any indirect preventive effects.

LEGAL STRATEGIES AND A MODEL LAW

What are some legal devices that might facilitate or burden institutional decisions?

Legal burdens of proof predispose legal outcomes against one party to a dispute unless there is evidence to the contrary [35]. Burdens of proof address both who must generate information in a legal dispute and make it more difficult for that party to legally accomplish what is sought. There are at least two kinds of burdens of proof – the burden to produce evidence (assigned to the party who must generate information – or proof – in a legal case) and the burden of persuasion (an assignment of responsibility to a party to provide sufficient proof, or to remove uncertainty, to the satisfaction of the fact-finding body – typically a jury). A burden of proof rule is a normative statement legally assigning evidence-production and persuasion tasks in order to change the current legal *status quo*. In the law typically the legal *status quo ante* continues, unless sufficient evidence is produced and uncertainty removed to warrant legal change [35,36].

A common, but not the only, reason for assigning both burdens of producing evidence and persuasion, is to assign it to the party who is in the best position to have the information to resolve the factual and legal issues in question. Surprisingly, however, this reason is almost always outweighed by other social considerations, such as placing the burden on one who would change the *status quo*, protecting a person against self-incrimination, protecting the party with predominant interests at stake, etc. [35]. Aperson who has committed a crime (or tort) has the best information about the illegal act, but the state (or plaintiff) has both the burden of production and persuasion to establish guilt (liability in torts) for a host of social policy reasons. Burdens of proof in regulatory contexts may not have been assigned to the parties with access to the best information based on mistaken analogies with the criminal or tort law, but there are good reasons for them to have this burden.

Burden of proof rules also predispose legal outcomes: the party with the burden of production loses, if he/she cannot produce enough information relevant to the case; the party with the burden of persuasion loses, if too much uncertainty remains to convince a fact-finding body, typically a jury (some aspects of Precautionary Principles resemble burden of proof rules. According to the UN PP the fact that decision makers have failed to remove all scientific uncertainty is not a reason for inaction, not a reason for not changing the *status quo ante*) [36].

Legal standards of proof. Legal standards of proof are the specified degrees of certainty that a decision maker must have before finding that the party with the burden of proof carried it [37]. Standards of proof specify how much uncertainty must be removed (or how much uncertainty

may be tolerated) in order to change some aspect of the legal *status quo*. In the US one of the more demanding standards from the criminal law is that the moving party, the state, must establish its case "beyond a reasonable doubt." In civil litigation the plaintiff must establish her case by a "preponderance (or balance) of the evidence." Various Precautionary Principles have features that resemble standards of proof. They are social decisions about how much certainty must be demanded (or not required as the case may be) in order for a decision maker to come to a legal decision [36].

Legal presumptions. Legal presumptions are legally required inferences once certain facts have been established. Rebuttable presumptions create a legal inference, unless an opponent produces evidence to the contrary. Nonrebuttable, or conclusive, presumptions do not permit rebutting evidence. In the US "adults are presumed sane; a person's disappearance and 7 years of absence creates a presumption of death; a child born to a married woman living with her husband is presumed to be his" [37].

Pre-market v. post-market statutes. Pre-market statutes might have provisions that require the screening of products (or substances) before they enter commerce, in order to prevent adverse consequences occurring from exposures, or they might have pre-market notification requirements – in the US requiring notification of the EPA of chemical substances proposed for manufacture, any results of tests performed, and its chemical structure [13]. Typically, a good screening statute would require that the manufacturer of a product test it for many adverse health and environmental effects, submit those results to an agency and bring the product into commerce or expose the public only after the agency is satisfied that it does not pose certain legally specified risks. In the US aspects of the US Food, Drug and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act, are screening statutes. Provisions of the Toxic Substances Control Act (TSCA) have notification features [13].

Screening laws, like the pre-market approval requirements for new drugs or food additives in the US can serve the aim of primary prevention of harm toward their objects of protection, if they function well and are enforced, because they require manufacturers or registrants of products explicitly to test for and report potential adverse effects of products. The test results are then reviewed by the Food and Drug Administration (FDA), which then decides on permitting the product into commerce, if they are judged safe enough.

A model pre-market law. I suggest in outline a model law based upon the idea of a good pre-market screening statute to provide ideas to guide a precautionary and primary prevention legal agenda (this model draws on various features of existing US screening laws, as well as reporting features of others, but is not meant to replicate or comment on actual laws). It also serves as a foil for assessing other strategies, for suggesting ideas about what might be needed in a more precautionary world, what is left out, and what has been lost from a more preventive approach to addressing potentially toxic substances.

A model pre-market screening law might include the following precautionary features. It would place on the manufacturer a reasonable burden to produce evidence about the short and long-term human health and environmental effects of substances or products that would enter commerce. It would place a burden of persuasion on the firm to show to some standard of proof (by a preponderance of the evidence or perhaps in unusual cases, beyond a reasonable doubt) to the satisfaction of an agency, analogous to the US FDA, that the substance or product was appropriately "safe" or posed "no significant risks" (where these would need specification) to the public, the workforce or the environment. A substance would not enter commerce until it had agency approval and its continued presence in the market would be conditioned on its being "safe" or exhibiting "no significant risks". It could be expeditiously withdrawn if evidence arose that falsified the condition of approval. Moreover, the firm would have an affirmative legal duty (not left to voluntary compliance) to report evidence of adverse effects to the agency (as a few US laws do). Finally, firms could be required to post substantial bonds for accidental or continual damages, if either is appropriate, in order to ensure that firms consider upfront the downside costs of their products [38].

Several ideas motivate this model. It better serves the aim of primary protection of the environment and public health than post-market laws. To this extent it resembles primary preventive aims in medicine and public health. It also rests on a principle of fairness: it is fair to make a firm to whom advantages will flow from introducing a product in uncertain circumstances and over which risks it has control to bear responsibility for removing uncertainty about the product and to bear losses that may occur if the uncertainties materialize into adverse outcomes [39]. At present the general public and the workforce typically bears the costs of uncertainties (or actual harms) – in the form of disease and monetary costs – from substances about which they have no knowledge and over which they have no or little control.

The model suggests several more precautionary ideas and protections. It provides for knowledge generation, provides for pre-market review by an impartial body for adverse health and environmental effects, and restricts exposure until agency approval is granted. It suggests the need for quick withdrawal of the product even after it is in the market, if adverse effects appear. Finally, it would impose on firms an affirmative duty to generate and report data about adverse effects (analogous to some feature of some US laws). One could imagine that such a law might also have a general duty clause, as Sweden has (discussed below), to require firms to carefully consider more benign environmental and health alternatives to their products and substances. How protective actual pre-market laws will be dependeds upon the particular features of the statutes in question and how they are implemented.

Such laws would require individual manufacturers of a product to generate health and environmental information contemporaneous with creation of the product or substance. This helps identify to the manufacturer any adverse effects, which then could result in some self-regulation or alternative product development in addition to serving governmental/public purposes. Generating health effects information contemporaneous with the creation of the substance also decentralizes the knowledge-generation task, distributing the burden as it were, and would represent some improvement on the *status quo*, where the vast majority of substances have come into commerce without screening and with little required testing. Creating timely health effects data would help prevent the current circumstance in which countries find themselves, largely ignorant of any toxicity properties of large numbers of commercial substances.

Pre-market statutes ensure that there is no or very little health and environmental exposure to substances until an agency is satisfied that there is no legally specified level of risk from them and permits them into production and commerce. With sufficient agency review and approval authority there is an independent body to assess the quality of health and environmental evidence and to help assure that the substance does not enter commerce if it presents significant risks to health or the environment. Thus, a model screening statute would provide better primary protections for human health than is often the case. Of course, such laws would need to be well implemented, which does not always occur.

In addition, a model statute would authorize expedited withdrawal of products from the market when there is appropriate evidence from adverse reaction reports showing that the condition of approval no longer obtains. This would be a protective device that, well implemented, might be an improvement on many post-market statutes that require data-intensive findings of adverse effects before they are subject to regulation. Such withdrawal provisions, suitably designed should be comparably quick. How such provisions would compare with existing laws cannot be pursued here.

In considering model pre-market statutes, one should consider laws structured for different products and risks. This would provide different "tiers" of testing, product review and approval, if scientific evidence would support scientific and legal presumptions that substances with some properties are comparatively safer than others. The US National Academy of Sciences Report on Transgenic Plants suggests something of a "tiered" strategy for addressing transgenic plants depending on the risks in question [40] and there is something of an implicit tiered response under aspects of TSCA, depending upon whether an existing substance is produced in high volumes and has substantial human or environmental exposure (nonethe-

less, under appellate review, there can be a comparatively high burden of proof) [41].

Of course, such laws, even those concerning approval of new drugs in the US, do not always function well, so they are not a panacea. The Food, Drug and Cosmetic Act in the US provides reasonably good, but not the best, protections from adverse effects of drugs and food additives. However, in the US even when drugs are subject to pre-market testing, some firms deliberately or negligently withhold information from the FDA (but at least this opens them to liability). Moreover, even double blind clinical studies on small groups of people are inadequate to identify all adverse effects from longer-term exposures in large biologically diverse populations. Somewhat more than 50% of the drugs approved in the decade from 1976–1985 "had serious post-approval risks that went undetected" in the pre-market testing period, but were discovered once they were in the market and more diverse and larger populations were exposed [42]. Thus, there is a need for substantial post-market follow up by firms to produce data about any adverse effects from widespread exposure and report results to agencies.

Post-market statutes. Post-market statutes, contrasted with pre-market statutes, provide for "regulation of substances after they have been in commerce and people have been exposed to them" [13] (in the US substances subject to post-market statutes might or might not have been subject to some screening or pre-market notification before entering commerce, depending upon their date of entry and laws in effect at the time). Once in commerce, substances have whatever benign or adverse effects they might have until the government or other entity (such as a private tort law suit) identifies adverse effects and moves to reduce exposure. Firms no doubt value the freedom to innovate and create products, free from governmental oversight until adverse effects occur and the lower cost of developing products, but such laws function to treat humans and the environment as experimental subjects to detect adverse effects and have other problems as well.

There are some distinctions, however, between post-market laws that highlight some more and some less protective features.

At the opposite extreme of model pre-market screening statutes are post-market laws that require governmental agencies to provide science-intensive justifications for ambient exposure concentrations of substances before they can be regulated. Such laws typically require an agency to identify adverse effects and then set safe exposure levels, perhaps decide what emissions or technologies will achieve the required level of risk or safety, and then to justify them with sufficient science and engineering studies to satisfy legal burdens and standards of proof as well as appellate review by courts. These greatly burden the production of information and slow regulation. They give firms structural incentives not to produce information, to keep substances in commerce and leave them there until the information is generated, to frustrate the prevention of harm, and to exacerbate the asymmetries of knowledge (by insisting on more certainty of risks or harms) [18,34,41]. If substances have not been well tested, their risks and harms not sufficiently documented, or the regulatory process is slowed, products remain in the market, generating revenues. This provides firms with strong incentives to resist testing and regulation. Legal and scientific burdens of proof, increasingly high scientific standards of proof and stringent court review in the US have made it quite difficult to address harm or threats of harm [29]. (Post-market statutes that permit agencies to regulate "on the frontiers of scientific knowledge", to issue regulations with "ample margins of safety" and to protect particularly "susceptible subpopulations", e.g., children or other especially sensitive groups, moderate a few of the burdensome features of post-market statutes, but do not address evidence production or ambient exposure burdens. Other modifications are suggested below).

By contrast, technology-forcing laws permit somewhat more expedited protective measures to be instituted once a harm or threat of harm is identified. Such laws permit agencies to identify toxicants as harmful to humans or the environment and then to require firms emitting them to use the best-available technology to reduce the substances to the lowest level the technology can achieve. While such statutes ease some information-generation and permit quicker responses to threats of harm – except for tech-

nology phase-in periods – agencies must still identify the harm or threat. Even the best technology may not achieve all the protection that is needed; it may need to be supplemented by other legal requirements as the US Clean Air Act is [13]. There is an added benefit to technology-forcing laws: firms often find substantial economic benefits from being forced to utilize the new technology, making such laws a win for risk reduction (and harm prevention) and economics.

The legal devices and strategies just sketched provide a background for further suggestions and indicate some generic strategies that might be utilized to create other legal approaches for pursuing the aims of the Precautionary Principle. As noted elsewhere "just as in the law when social decisions are made about standards of proof, burdens of proof, or legal presumptions, in a democracy citizens can rightly choose to decide similar issues concerning [legal] precautionary actions to prevent threats to their health or the environment" [36]. Consider how some of these might be combined to serve some of the aims of primary prevention and precautionary strategies.

REMEDYING IGNORANCE

If little is known about the universe of toxic substances and we have little systematic knowledge about human effects on the environment, how can this be rectified? In the US there are significant problems with existing substances that have not been well tested and these are typically subject to post-market statutes. The model law sketched above suggests some ideas for post-market contexts to address some of these problems.

First steps: providing inventories and monitoring

In order to take precautionary and preventive actions, we need to know the current condition of public health and the environment. The concept of precaution provides reasons to have inventories of the *status quo*, as well as scientific and social evaluations of them; what scientists and policy makers do not know can hurt us. What inventories of the current state of the environment and public health are needed to take a more precautionary approach to protect public and workforce health, to remedy current problems, and to develop the kind of world in which we want to live?

Providing inventories are tasks for both the scientific community and the law. The scientific community may be motivated to do some monitoring as part of investigator driven research. However, concern about the public and workplace health may go beyond the particular (private) research interests of the scientific community and be of community or public concern. If it is a concern of the community as a whole to know about the collective condition of public or ecosystem health, it could be codified into appropriate legal requirements.

In the US some of these monitoring tasks can perhaps be accomplished within existing regulatory authorizations, e.g., under statutes enforced by the EPA or the Occupational Safety and Health Administration, but it is likely that additional authority would be needed. In the European Union, there may be better legal devices for conducting such monitoring.

Other monitoring tasks might include the following:

Monitoring for diseases. Countries could create or expand disease registries in order to provide for early warnings of or changes in disease patterns. This would be especially appropriate for susceptible subpopulations, such as children (the aim would be to provide registries of childhood cancer, reproductive, neurological and other diseases), the elderly (since in most advanced industrial countries populations have an ever larger elderly population), those already diseased, e.g., asthmatics, or those exposed for a working lifetime in an industry of concern, e.g., monitoring of retired workers [15]. Monitoring provides snapshots of current incidence and death from disease, geographic distributions of disease, and other information valuable for communities to assess the current public and workplace health [1,43]. It would support epidemiological studies, which would, in turn, foster further research to help protect susceptible subpopulations.

Monitoring for exposure effects. This might include inventories of impacted communities (similar to some at the US Agency for Toxic Substances and Disease Registry, but expanded), inventories of critical pathways of expo-

sure such as breast milk [4], or, since we now know that some substances are lipophilic, random sampling of the body fat of the populace to remain informed about what is accumulating in the bodies of the general population. It could also include monitoring of the blood and urine for listed substances as the Centers for Disease Control is doing [44].

Such monitoring might also apply to low socio-economic communities that experience exposure to multiple toxicants that make them vulnerable to adverse health effects. A similar registry of communities with high disease rates, even if causes are unknown, might reveal groups who are already vulnerable and in need of precautionary action to remedy existing problems and prevent future ones [45].

Beyond legally authorized inventories and evaluations of the *status quo,* what legal strategies might there be for affirmatively generating knowledge about the substances or products that could harm us and for providing quicker reactions to actual threats of harm?

Comparisons with the pre-market model for knowledge-generation

Some of the features of the model pre-market screening law provide ideas for how to address problems of existing chemicals and some shortcomings of post-market laws.

Affirmative knowledge-generation. It is impossible, but probably not necessary, to remedy all current ignorance about the large universe of substances in commerce. Interestingly, however, the European Community has initiated a process to require testing of 30 000 substances in commerce and to restrict 1500 of the substances posing the greatest risks [46]. Some substances pose few or no problems and remedying the ignorance about the large numbers of substances about which little or nothing is known would probably be impossible. However, to address critical knowledge gaps and to prevent adding to the universe of substances about which we know little will require more affirmative knowledge-generation. Lack of knowledge about the chemical universe may or may not mask serious adverse effects. Nonetheless, the mere fact of ignorance is a substantial concern. If we want to be forewarned of threats to human health or the environment in order to reduce risks and prevent harm, we will need affirmative knowledge-generation about existing substances that enter commerce, and better knowledge-generation about substances already in commerce, a much greater problem.

A pre-market screening law like the model could address any future problems that might arise and could have prevented some problems that arose from past practices. The more difficult problem is remedying scientific ignorance about substances already in commerce; what legal mechanisms might assist in this?

Volume triggers. If a substance were produced in large amounts with non-negligible exposure, this provides a reason to test it, if the scientific community is otherwise largely ignorant of any toxicity properties. Having a volume requirement to trigger testing provides an automatic precautionary approach to obtaining information about the effects of the high volume production of substances. The EPA entered into voluntary agreements with manufacturers who produce 3000 substances in the highest volumes in the US [16], but my suggestion is different. The idea is that once a substance is produced in an amount exceeding X pounds (which would need to be specified), the firm would automatically be required to pay for testing by an independent laboratory. This distributes knowledge-generation, produces knowledge, and does not require an agency to issue a rule to require testing, eliminating burdens and standards of proof for the government.

Credible-scientific-evidence-of-toxicity triggers. An analogous mechanism might be a testing requirement that could be triggered if independent researchers acquired credible scientific evidence that a substance posed toxicity problems, which an impartial agency could review [36]. If the evidence were plausible, the agency could then quickly require the manufacturer to pay for further testing by an agency chosen laboratory. For example, in the US there are several substances for which toxicity properties are of concern to agency personnel – polybrominated diphenyl ethers [4], bromopropanes [5], and some phthalates [6] that perhaps currently should be subject to such requirements; perhaps these could have been identified earlier.

Such triggers would create legal mechanisms to give public agencies the authority to obtain information and

determine any toxicity problems before they fully materialize. Such laws could also shift the burden of proof to the manufacturer of the substance once a credible warning had been raised – to pay to provide information and to exonerate, if it can, the substance in question. The idea is to trigger and expedite firms' testing of products already in commerce without agencies having to satisfy elaborate and burdensome regulatory procedures. Once testing was completed, that information should become part of the public record, since it is for the protection of the general public.

Toxicity-characteristics triggers. Analogously, agencies could create lists of characteristics of substances that at present were known to pose toxicity problems, and if substances had these characteristics, agencies could require appropriate testing of them, if there were not adequate health and environmental information. Examples, *inter alia*, might include substances having plausible chemical-structure biological-activity relationships to known toxicants, being strongly mutagenic, or binding to the Ah receptor as does dioxin. If plausible similarities were identified, there could be legal procedures by which manufactures could be required to provide the needed information. If there were sufficient similarities, there would be no need for further testing, as may be the case with PBDEs [4].

Analogously agencies might require firms to do more testing and reporting of substances for high chemical reactivity or agencies might compile lists of highly reactive chemicals. Both strategies aim at firms developing chemical processes that would have lower risks from explosions caused by combinations of highly reactive substances [47].

Broadening knowledge triggers. There may be other features of substances justified by the scientific findings that could trigger testing.

There is, however, a point to be made about legal procedures. If it is too difficult for an agency to require the testing, post-market procedures will not be effective. Consequently, agencies would need procedures by which testing could be fairly easily and quickly authorized (even better, if testing procedures were automatic, as volume triggers could be, they would be more effective). In the US, there are post-market testing provisions under the TSCA, but they are sufficiently difficult to utilize that there has been quite limited use of them [41]. Nonetheless, some of them are suggestive. A US court has held that "if there is more-than-a-theoretical basis to suspect the presence of "unreasonable risk of injury to health" and a "more-than-a-theoretical basis for inferring the existence of some exposure", the EPA may issue a rule to require a manufacturer to provide further toxicity testing in order to determine if there is an "unreasonable risk to health" [48]. Combined, these constitute reasonable triggers. The principal problem with this provision is that the requirements for issuing a rule are sufficiently burdensome that it is not frequently utilized [13,49]. If legal barriers to issuing a rule were eased, a feature similar to this might provide part of a reasonable model (but it still does not have automatic testing triggers).

Similarly, there might be some legal mandate for firms to identify knowledge gaps or features of substances about which they were ignorant with respect to adverse health or environmental effects, as the European Environment Agency suggests [20]. This would be especially important for substances produced in high volumes. This would be another reminder to firms to attend to areas of research that are often overlooked or de-emphasized, and it may provide a basis for other legal action should the substance turn out to be a human or environmental toxicant.

The above knowledge-generating suggestions address basic toxicity and reactivity testing, a first and important step, but not the only area about which there is considerable ignorance. Even if substances are known to be toxic, further information would be needed about exposure and there would be a need to provide protective actions.

Generating exposure information. Post-market laws modeled after California's Proposition 65 could address some of these issues. This citizen-passed initiative creates a list of known carcinogenic or reproductive toxicants (it is the responsibility of the California EPA to provide information and regulatory justification for this – contrary to a pre-market statute or one with comparatively automatic testing procedures), and then places a legal burden of

production and persuasion on manufacturers or users of the substances to show that the public is not exposed to concentrations of substances that pose "significant risks of harm". If there are significant risks from exposure, firms must decrease them below legally specified levels [50]. Finding the toxicity information needed to create the list is the responsibility of a state agency, and, thus, given the backlog of substances and limited resources of agencies, lacks significant precautionary features. Nonetheless, this law gives producers or users of known toxicants a legal reason to generate exposure information and take protective action once a substance is on the toxicity list instead of creating structural incentives to resist such actions as occurs under post-market statutes. Moreover, citizens, through a "vigilante" provision, may identify legally excessive exposures and can bring a citizen action to require enforcement of the law (and receive a portion of the fines, if the state does not).

The above discussion has been premised on the idea that a primary prevention and precautionary approach to addressing human health risks would require firms themselves to generate health effect information simultaneous with creation of products (under pre-market statutes) or in post-market contexts to generate such information on the basis of relatively quick procedures by means of several different possible legal devices.

However, in a further departure from some of the ideas of pre-market information-generation and protection, agencies under most post-market statutes might be required to find information about and justify the identification of toxicants for regulation, largely the current situation in the US. Even if this is the case, there are nonetheless legal devices that could aid knowledge-generation and protective action.

Legislatures could authorize agencies to develop expedited identification procedures, if the science supports such a suggestion – for example, using various short-term toxicity tests – in order to identify toxicants without requiring so much data-intensive research. The aim would be to find tests that are "accurate enough" for preventive purposes to ensure that there are not false negatives and underregulation, yet not generate so many false positives or result in so much overregulation as to cause overwhelming political opposition [51]. If a society is burdened by post-market regulatory procedures, some of the costs in time and resources could perhaps be mitigated by utilizing expedited carcinogen or reproductive toxicity tests in order to identify substances for regulation quicker. Or agencies might develop presumptive information that substances have adverse human health properties (and that has legal effect), and then place a burden of production and persuasion on the firms to generate data to rebut the presumption if they can [21].

Moreover, there may be reasons to identify toxicants as needing regulatory attention by means of tests that fall short of identifying them as human toxicants. For example, perhaps firms should not be releasing large numbers of mutagens into the human and natural environment, even though scientists are not certain which of several mutagenicity tests identify human mutagens or carcinogens. Appropriate positive mutagenicity tests may provide a sufficient reason to refrain from releasing such substances. Animal studies are also useful, but they are slow (more below).

Legislators might also authorize agencies to create lists of "Substances of Concern" for the guidance of citizens and firms alike. Firms could react to such lists by reformulating or changing products or processes or looking for alternatives to current product directions; citizens, so informed, could take steps to protect themselves. Such laws would risk controversy because substances could be tarred by adverse publicity and in the US this would risk legal invalidation. Moreover, such laws would have limited effectiveness in motivating firms to withdraw products from the market, given recent evidence about firms' such actions concerning drugs [52]. However, if firms generated more health and environmental information upfront about their substances before commercial commitment, this would tend to reduce adverse effects.

PROVIDING PRECAUTIONARY PROTECTIONS

One of the most serious problems in contemporary regulatory climates for post-market regulation is that protective

regulatory responses tend to be slow and exacerbated by "paralysis by analysis". Thus, any protective aspects of post-market laws are hindered by the information- or science-intensive nature of legislative or court-imposed burdens of proof, standards of proof and data requirements. Even though post-market statutes tend not to be as protective as good pre-market screening statutes could be, their effectiveness can be increased by easing some of the information requirements and shortening their response times. The discussion that follow provides suggestions to attenuate or mitigate the cumulative effect of a number of epistemic, political and legal considerations that asymmetrically tend to preclude discovery of adverse health effects from toxic substances in post-market contexts and, thus, to hinder preventive action. Post-market laws result in substantial problems as the US chemical regulatory history suggests, so any recommendations for improving them may have limited effects.

Moderating the burdensome effects of post-market statutes. One step in furtherance of a precautionary agenda would be for agencies to adopt standards of proof for regulatory science under post-market statutes to allow for expedited regulation. This would permit quicker responses to identified harms or risks of harm. The idea would be to modify extremely demanding and data-intensive scientific standards of proof when reasonable scientific evidence on the frontiers of scientific knowledge would be sufficient. Statutes could be written to permit regulation "on the frontiers of scientific knowledge" when evidence presents a "reasonable basis" that a substance poses a risk. Such a post-market law would ease some of the current burdens on regulation in the US.

California took a step in this direction with expedited potency assessments under Proposition 65 (just one of the regulatory steps in a post-market risk assessment). It permitted the California EPA to issue potency assessments for carcinogens on the basis of close scientific approximations to literature- and science-intensive potency assessments. Potency assessments that once took 1/2 to 5-person years per substance were shortened to two days per substance, except in very unusual cases in which a closer examination was required [53,54]. Agencies and courts can mistakenly demand more and better data and justification for regulation, when it may not be necessary in the context. Moreover, the expedited potency assessments were in closer agreement with California's science-intensive potency assessments than were science-intensive potency assessments generated by the California EPA and the US EPA for the same substances. The expedited potency assessments were both accurate and much quicker than standard science-intensive assessments done by two different agencies.

As another example, agencies should be prepared, as some are, to regulate on the basis of animal studies alone, or animal studies plus mechanistic data, when good human data are not available (as is usually the case) [55], although in the US agencies often appear close to demanding human evidence for regulation. However, there are limits to the precautionary effects of this suggestion, since generating animal data takes 7 to 10 years, is costly and takes substantial scientific resources. With about 1000 new substances entering commerce each year and as few as 7 animal studies begun each year by the US National Toxicology Program, testing only falls further behind the production of new chemicals, arguably increasing the ignorance annually about the universe of substances [56].

To the extent that statutes in the US would permit expedited procedures to be adopted by regulatory action, there are presumptive reasons to do so. However, they would need supportive courts to review the regulations and uphold them. Other countries might find a more hospitable court system for such initiatives.

Moreover, if statutes actually require risk assessments, agencies could adopt, as is done to some extent in the US, default safety factors, high upper confidence extrapolation models and presumptions (analogous to legal presumptions to reduce data-generation) to ensure as a matter of law (without demanding scientific confirmation of the point) that there are sufficient protections for particularly susceptible subpopulations – e.g., infants, the elderly or those already highly exposed to substances – to account for a sufficiently wide range of variability in the general population, and in general to address some data requirements as a matter of policy [57]. Such legal presumptions

would take the place of data-intensive demands that could be required for variability and susceptible subpopulations. Utilizing default standards is a perfectly respectable social decision that can be made within a legal system, much as the law creates legal presumptions.

Of course, less science-intensive information is needed for technology-forcing statutes than under statutes that require the setting of specific ambient exposure levels. As indicated, more use could easily be made of such statutes.

Generic regulation of risks or threats. Legislatures could authorize more generic regulation of risks and harms. For example, laws could authorize the adoption by incorporation of regulations issued by other agencies, or the identification of toxicants by other agencies (e.g., California's Proposition 65 regulations permit this for the identification of toxicants) in order to expedite protective measures, instead of requiring each agency to reinvent a science-intensive regulation. For instance, an agency in one jurisdiction as a legal presumption could adopt regulations from other jurisdictions and give them legal effect, but provide for the presumption to be reviewed if legally compelling problems arose. Legislatures could authorize, or agencies may have authorization for, and courts could uphold, reasonable generic regulation of substances like some that have been attempted (but not succeeded) in the US. A more health-protective court could have reasonably upheld the US Occupational Safety and Health Administration's generic regulation of 428 air toxicants based on existing consensus standards, instead of striking it down for want of risk assessments on 5 of the 428 substances [27].

The best means of moderating the burdens of post-market statutes is to reverse the usual burdens of proof that are usually present, as has been done in modest ways by California's Proposition 65 (described above).

Analogously, for either pre- or post-market statutes, one could compile either a list of substances known to be toxic (e.g., known carcinogens or reproductive toxicants as under California's Proposition 65) or a list of characteristics of substances known to have posed problems in the past, e.g., a tendency to persist, bioaccumulate, be mutagenic, be lipophilic, act by a common metabolite (as so the vinyl halides or benzidine dyes) or bind to the Ah receptor (as does dioxin), etc. (in the US some of this occurs as a result of the EPA's use of structure-activity review of new substances) [13]. Under post-market statutes one could then require firms to show that exposures to actual toxicants did not pose significant risks to human health or the environment (somewhat like Proposition 65) or face exposure reduction or phase-out. For substances possessing problematic characteristics firms could be required to overcome some burden of proof and show that substances with such features did not pose risks to either human health or ecosystems and, perhaps, to post a substantial bond until the issue is clarified [36]. In absence of sufficient showings of no significant risk, the substances would be subject to phase out. Such statutes would utilize analogies to existing knowledge, expediting information-generation, with phase-out provisions increasing protections.

Follow Sweden. Finally, as I have argued elsewhere, one could look to a country such as Sweden that appears to have a more thoroughgoing precautionary record as a further model for suggestions**.** Many of the burden-shifting and standard-of-proof-reducing strategies suggested above have been adopted in Sweden as attempts to reduce the damage to human health and the environment. Generic strategies in Sweden include "a general obligation to investigate, as far as possible, the effects of the product on man and the environment,... to label the product and to inform all users as carefully as possible on measures to be taken to protect man and the environment during use and disposal of the product,... to (reduce or eliminate) to the extent possible substances in the product that make it hazardous,... (to find substitutes for hazardous substances and to utilize them) if it is possible to produce acceptable alternatives with smaller risks" [58]. A legislature could impose such general duty requirements on firms even in post-market contexts (such a suggestion has been made for US tort law) and hold them accountable for failing to follow its general prescriptions. In Sweden once there is a scientifically-based suspicion of risks from a product, the producer has the burden of proof to "show beyond a reasonable doubt, based on existing scientific knowledge and principles, that the suspicion is unfounded... and any

remaining uncertainty about its hazardous properties must be borne by the manufacturer who wants to market the product, not the public" [58]. Enacting such a statute will be difficult in many countries because of the political forces involved. However, the Swedish model may serve as a useful example of how some of the problems of serious threats to human health and the environment should be addressed.

Personal injury law. Even though personal injury law is a post-market legal device with retrospective remedies, it has relatively modest deterrence effects that can be either enhanced or frustrated by how it functions. In the US as a first step the tort law could function better if courts would admit all the evidence and respectable expert testimony that the scientific community recognizes, instead of imposing comparatively high standards of admissibility counter to respectable science as some courts have done [34]. This would slightly ease procedural, admissibility and access barriers for victims in the tort law so that it could have a greater deterrent effect on corporate behaviour [29,34]. Beyond this, courts could develop doctrines of reasonable fear of cancer (and other diseases) as well as actions for medical monitoring (making them comparatively easy to establish in torts) in order to achieve some secondary and tertiary precautions toward those already exposed to known toxicants, two causes of action that have had limited use in the US [59–61]. The first reinforces a basic tort law cause of action, but could be made easier to prove, while the second provides some protection for those with exposure, but not yet diseased.

Finally, a much more precautionary approach would be to create "a new tort that conditions culpability on the failure to develop and disseminate significant data needed for risk assessment" (emphasis added) [18]. Once plaintiffs established "manufacturers' negligence in failing to reveal substantial information highly relevant to assessing the potential risks of (toxic) exposure, a *prima facie* case of liability would be made out for those able to substantiate exposure and ill health" [18]. This will not make the tort law as effective as a pre-market statute could be, but the presence of more precautionary causes of action might enhance some of the deterrent effects of current law and increase firms' motivation to more fully test substances before the public and workforce is exposed to them.

CONCLUSION

Creating a legal agenda in the service of primary prevention of, and precaution toward, harms and significant risks to human health requires more inventories and better monitoring of the state of public and workforce health than at present. Rectifying problems of the past to better serve the aims of precaution will require much more affirmative knowledge-generation by those who create and use potentially toxic substances, improved pre-market review of substances, better responses to early warnings, decentralized information-generation by manufacturers, and quicker protective post-market responses to evidence of toxicity. The model pre-market screening law has been conceptualized to suggest ideas to guide legislation or serve as a guide for modifying post-market legislation to better serve the aims of precaution and primary prevention of harm. In this it provides a kind of model toward which to aim (other approaches aiming at similar goals involve changes in industrial inputs, final products and process technology; in short, pollution prevention, but lack of space precludes any discussion of these points) [62]. Although retrospective personal injury law does not have the best mechanisms of precaution, even this can be much more protective than it is at present by enhancing causes of action for reasonable fear of disease and medical monitoring and moving to create new causes of action for failure to develop and disseminate the information needed to assess the toxicity of substances.

I make the above suggestions in order to provide ideas for a more preventive and precautionary strategy toward risks that are created by a free enterprise system that largely seems out of control. Unless some of the more significant suggestions are followed, we will have to rely upon time-consuming, corroborative science in legally difficult circumstances to confirm on a case-by-case basis against powerful political groups and difficult legal burdens of proof that there are significant risks or actual harm to the public or workforce. This is hardly an agenda of primary

prevention toward environmental and workplace health risks or an appropriate stance with which to enter the twenty-first century faced with new and so far untested technologies.

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