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BRIEFING

Precaution Can Kill:
Chemical Benefits and Regulatory Risks

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INTRODUCTION

Regulation of chemicals is as ubiquitous as chemicals themselves. Wherever a chemical component is used, a regulatory requirement or procedure governing that use is likely to be found. Intervention, whether in the form of law or regulation, often is justified on the grounds of preventing harm associated with inappropriate use or excessive risk. However, regulation is also known to be accompanied by various costly risks.[1] Owing to the difficulty of assessing risk accurately, particularly the risk of chemical hazards, burdensome or misaligned regulation can result in detrimental consequences for innovation, the economy in general, and human morbidity and mortality. While regulations seek to reduce the risk of death and other harms, the added costs of regulation can have the unintended effect of stifling higher probability risks, leading to lower personal incomes and, in turn, increasing the risk of mortality and other harms.[2]

Effectively assessing the level of regulation needed, if any, requires articulating some standards or set of goals for the regulatory regime and eliminating fear-mongering and hyperbole, which are extremely common in the regulation of chemicals. Different jurisdictions rely on distinct regulatory regimes to address the risks inherent in the use of chemical compounds: The European Union (EU) has adopted the precautionary principle, which regulates chemicals on the basis of potential hazards; while the United States (US) attempts to consider the potential benefits of chemical use by employing a cost-benefit analysis to determine the appropriate level of regulation. Due to the inherent complexity of chemical interactions and the possibility of delayed health and environmental effects, both regulatory approaches are susceptible to magnifying the potential harms of chemical use. These regulatory approaches also face the risk of causing increased prices, shortages, or reduced efficacy of products. This is problematic if the goal of regulation is to minimize the cost of risk and maximize the benefits to consumers and producers.

This briefing provides an examination of both the standard precautionary principle and cost-benefit analyses as methods of regulation; it suggests that both approaches have substantial problems in addressing the risks associated with the use of chemicals. A common law approach is proposed as an alternative for dealing with risks associated with chemical use. The following sections outline each approach and explore the effectiveness of regulation and litigation at achieving their goals. The briefing concludes with a set of illustrative case studies that highlight these issues.

APPROACHES TO REGULATORY POLICY

The goal most commonly associated with regulation is minimizing the risk to the public. Risks—especially those associated with chemical use—are difficult to measure, both because the events they concern are rare and because the costs of adverse events are difficult to quantify. Chemical risks are more difficult to assess than

other areas of concern due to their pervasive presence across products and activities and the potential for delayed impacts on human health. As noted, policy regarding the risks associated with chemical use can take one of three forms: ex-ante direct intervention based on the precautionary principle, which is the standard in the EU; ex-ante direct intervention based on cost-benefit analysis, which is the standard in the US and, to a lesser extent, Canada; or ex-post mitigation of risks through the incentives provided by common law doctrines, which is not widely used by any jurisdiction at the time of this briefing.

The Precautionary Principle

In 1991, the EU adopted the precautionary principle as the basis for regulating chemical use. The precautionary principle states that the threat of serious or irreversible damage creates sufficient cause for regulation, even if there is not full "scientific certainty." In Europe, the precautionary standard is used as a way of building a "margin of safety into all decision making."[3] According to Foss Hansen, Carlsen, and Tickner, the precautionary principle usually entails four components: "(1) taking preventive action in the face of uncertainty, (2) shifting the burden of proof or responsibility onto proponents of potentially harmful activities, (3) exploring a wide range of alternatives to possibly harmful actions, and (4) increasing public participation in decision-making."[4] Staunch supporters of the precautionary principle sometimes embrace an even stronger interpretation, mandating "that when there is a risk of significant health or environmental damage to others or to future generations, and when there is scientific uncertainty as to the nature of that damage or the likelihood of the risk, then decisions should be made so as to prevent such activities from being conducted unless and until scientific evidence shows that the damage will not occur." That interpretation nudges regulators to reject activity that bears any risk, no matter how slight; functionally, this creates an impossible burden to meet.[5]

Cost-Benefit Analysis

Section 6 of the Toxic Substances Control Act requires the Environmental Protection Agency to conduct risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." In determining if the chemical substance poses an unreasonable risk, the TSCA precludes costs or other non-risk factors in the analysis. In determining how to manage identified risks, however, at least two Executive Orders require US regulatory bodies to provide a cost-benefit analysis for any proposed regulation of chemical use.[6]

The four necessary steps in risk assessment are:[7]

1. Identifying the hazard – the danger or nature of the harm. For example, identifying a contaminant such as bisphenol A (BPA), and documenting its toxic effect on humans and the environment.
2. Providing an exposure assessment – determining the concentration of the contaminating agent in the environment and estimating the rate at which the human body absorbs or is exposed to the chemical. For example, determining the concentration of BPA in a plastic bottle and determining the average dose a person would absorb or ingest.
3. Assessing the "dose-response" – measuring the destructive effects associated with different levels of exposure.
4. Characterizing the risk – predicting the potential impact of a chemical based on the negative effects and the different levels of exposure.

While that four-step paradigm seems straightforward, chemical risks can be hard to quantify outside of controlled laboratory conditions. They are subject to time lags and

different levels of exposure at different points in the production and consumption process. A single chemical might be utilized by several different firms, with different production processes, for products with a variety of purposes. Those considerations add a level of complexity that an ex-ante regulatory assessment is unable to capture. What is more important, risk management is predicated upon first characterizing the risk accurately. Moreover, the public management of risk by regulatory mechanisms is subject to its own levels of complexity and uncertainty because of the knowledge and incentive problems prevalent in bureaucracies.

Beyond the risk assessment process, US regulators are (by executive order) to provide a cost-benefit analysis for all new proposed regulations that attempt to manage those risks. These analyses include economic impacts as well as other costs and benefits. For chemical regulation, the results of risk assessment reports must be included. Consequently, a cost-benefit analysis produces two outcomes that can be quantified: cost-effectiveness and net benefits. Importantly, net benefits are measured as the ratio of the estimated monetized costs to the estimated monetized benefits of the regulation. This ratio is then compared to the cost-benefit ratios for alternative regulations and for taking no action. By incorporating both expected costs and benefits into the assessment, a more objective measure of the net benefits is produced. A cost-benefit analysis, however, is only as good as the estimates underlying it. Regulatory agencies and the interest groups supporting regulation have strong incentives to overestimate the benefits and underestimate the costs.

The inclusion of a cost-benefit analysis in the decision-making process of how to manage established risks does not preclude the influence of the precautionary principle. Indeed, for some risks, the US has adopted a more precautionary approach than the EU. For example, while European regulators have been more precautionary about hormones in beef, US regulators have adopted more stringent precautionary restrictions for mad cow disease (BSE) in beef and blood donations.[8]

Chemicals-of-concern lists. Chemicals of concern lists have begun to be used with increasing frequency both in some US states (but not the US federal regulatory agencies) and Canada—an approach to chemical risk that is rooted in applications of the precautionary principle. These lists expand policy influence beyond the official federal regulatory approach and its substantive cost-benefit analyses of how to manage established risks. Although these lists create manufacturer reporting requirements or are generally presented as identifying chemicals that need further research, they have the side-effect of discouraging producers from using listed chemicals at all. In cases where the listed chemicals are associated with severe and highly probable dangers, the net effect of listing them improves social welfare. However, because being listed as a chemical of concern is often based on the potential for risk rather than provable risk, at least some listed chemicals do not have significant negative effects on the environment or human health; listing these chemicals can substantially reduce social welfare. Unfortunately, because firms are less likely to handle chemicals that are listed, it is unlikely that the actual probability or severity of risks will be discovered.[9] Thus, in practice, the regulatory approaches of the US and Canada, especially in states where these lists are used, move toward results that are closer in result than their divergent approaches might suggest.

Common Law

Litigation through the courts is a third viable mechanism for managing societal risks relating to chemicals. Common law doctrines, systems of jurisprudence where court decisions are based on the precedent established in previous court cases, can offer a flexible framework for regulating chemical risks and harms. Tort law (under the common law umbrella) is applied to

cases where one party (the defendant) injures another party (the plaintiff), and the injured is to be compensated for the injury after the proximate cause of harm is determined. In general, lawsuits under tort law can be predicated upon three different standards: nuisance, negligence, and strict liability.

Nuisance claims suggest that the defendant's actions caused measurable harm to the plaintiff and seek to establish compensation for those impacted. Many chemical risks can be classified as nuisances because the production and handling of a chemical causes harm to the public health or public order. Instead of assessing risk, the courts address the "gravity of harm" by considering the "extent and character of the injury alleged, the social value of the use invaded, and the burden of avoiding harm by the harmed party."[10] Similar to the cost-benefit analysis, the courts also consider the "utility of conduct"—analogous to the benefits—by considering the social value of the activity, the suitability of the locality to the activity, and the practicality of avoiding the invasion."[11]

Negligence claims suggest that the defendant unreasonably, but unintentionally, harmed the plaintiff. Considering what is unreasonable is the task of the court. The court must decide whether the defendant exercised reasonable care and whether damages incurred by the plaintiff are a direct result of the defendant's carelessness. For example, if a company fails to test their product for toxicity, a court can award damages based on negligence if the presence of toxins was foreseeable. Johnson & Johnson recently recalled 33,000 bottles of baby powder when regulators found 0.00002 percent of "chrysotile asbestos" in a test sample of the product. As a result, the company faces litigation from more than 15,000 plaintiffs.[12] The plaintiffs are suing Johnson & Johnson based on negligence claims, which, as described above, is a harm caused by the defendant's carelessness. Johnson & Johnson will be considered negligent if the firm failed to take the appropriate precautions in ensuring that its baby powder was free from asbestos.[13]

Strict liability, a more stringent standard relative to negligence or nuisance claims, "holds a manufacturer liable for all harm caused by its product and only requires the court to determine causation."[14] That standard does not require the court to establish negligence and would help mitigate generally accepted claims of abnormally dangerous chemical use risks. When customers may misperceive the risks, such as with the herbicide Roundup, strict liability could be an efficient standard. Monsanto, the developer of Roundup, is not required to disclose the product's full ingredient list. This information asymmetry shifts the burden of care away from users and onto the producer. Imposing strict liability in such cases supplies incentives for the producer to allocate more resources to safeguarding consumers from possible injury.

Liability regimes are not designed to eliminate all risks, but only the harms for which the cost of avoiding injury and death is less than the loss incurred by the victim should injury occur.

EVALUATING REGULATORY APPROACHES

The expressed goal of regulation, regardless of approach, is to minimize the risk of harm and maximize benefits to consumers. Regulatory approaches differ in their effectiveness at achieving this goal. Each approach has systematic advantages and disadvantages in how it attempts to manage different types of risk associated with the use of chemicals. Understanding how those advantages and disadvantages impact that goal is an important part of the policy analysis process.

Risk and Harm Mitigation

A clear understanding of the type of risk involved is important for assessing the potential harm to individuals. Claims of risk mitigation or elimination are often focused on harms associated with chemical use (Type I). This understanding of risk and harm is at the core of the precautionary principle. There is,

however, a second type of risk focused on harm associated with prohibition (Type II). In these cases, prohibiting the use of a chemical prevents individuals from receiving its benefits, imposing a different type of harm on the public. This type of harm is more difficult to observe, especially when the risks of using a chemical are not well-established or quantified. Unfortunately, risk associated with prohibition is explicitly excluded from the precautionary approach and often neglected in cost-benefit analyses. Both types of risk—the risk of failing to regulate and thereby harming individuals, and the risk of regulating only on the possibility of harm and thereby forcing individuals to forego benefits—should be considered in policy formulation.

Type I Risk and Harm. The three regulatory approaches differ in their ability to account for potential, yet unrealized, systemic harm from chemical use. The precautionary principle is most stringent with respect to accounting for such risks because, as mentioned above, any imaginable harm can (and most likely will) be considered by producers, who have more and better information about known and immediate risks than regulators. Cost-benefit analysis will result in the consideration of risks that are knowable by regulators and quantifiable, even when they are unrealized, but will not accurately account for risks that regulators cannot foresee or are highly improbable. The cost side of the cost-benefit analysis must discount risks by the likelihood of their occurrence. A highly unlikely adverse event will not have a significant effect on the predicted cost of using a chemical and will enter the cost-benefit analysis only if the regulator is aware of it. Finally, a system based on litigation alone, because it relies on the prosecution of realized harm, is blind to all unrealized future harms associated with chemical use.

Type II Risk and Harm. Regulatory approaches also differ in their ability to account for the unseen risk and resulting harm from taking regulatory action. Both the precautionary principle and chemicals-of-concern lists fail to account for this type of risk. Precautionary regulation, when negative impacts are uncertain or unproven, has the potential to harm consumers by reducing product efficacy or simply making many products unavailable. Further, while scientific findings can and should be used to inform the policy process, those processes are institutional and political in character, and are not simply the result of allowing the science to determinate what should be allowed or not.[15]

Cost of Regulation

The literature on the cost of regulation continues to expand. Regulatory costs are usually not distributed equitably. Small businesses and low-income consumers often are most sensitive to retail price increases associated with regulation; their smaller overall budgets make it more difficult for them to shoulder regulation's costs.[16] Some of the added costs of regulation, like taxes, are borne by both consumers and producers. Who bears the burden of the regulation is determined by which side of the market is least sensitive to price increases. If the regulated chemicals increase the cost of products that are of relative necessity to consumers, those increases come out of the pockets of consumers. Chambers and colleagues provide empirical evidence for this regressive effect of regulation on low-income consumers.[17]

Moreover, increased regulation has been shown to have regressive effects on wages. Bailey, Thomas, and Anderson find that compliance-relevant professions, like lawyers and accountants, benefit from expanding regulatory intervention, while workers in lower-paid professions earn less when regulation increases.[18]

The increase in regulation's costs and subsequent lower wages reduce disposable income that affect low-income households because public risk mitigation crowds out their ability to mitigate higher-probability health and safety risks privately. Risk-risk analysis finds that policies costing more than $35.7 million per life saved will not be beneficial from a health

standpoint.[19] Individuals find ways to mitigate risks privately as opposed to using the public mechanism. Higher-income households mitigate lower probability risks more than lower-income households. As income increases, individuals spend more to mitigate smaller-probability risks. That evidence suggests that lower-income households spend most of their safety expenditure budgets mitigating higher-probability risks.

Interestingly, regulatory risk reduction by public-sector agencies often involves the mitigation of small-probability, high-cost risks. For example, work-related fatalities, which chemical regulations sometimes target, happen with an annual frequency of only 0.2 in 10,000 people.[20] Rules regarding growth hormones in cattle feed, for example, were aimed at risks estimated to affect approximately 3.1 in 10 million of the exposed population. However, those regulations, like the rules regarding cattle feed, disproportionately affect low-income households.[21] They redistribute wealth from lower-income households to higher-income households by forcing lower-income households to subsidize the regulation of lower-probability risks, crowding out the budgets allocated to mitigating larger-probability risks. The costs to low-income households often are unseen because regulations intend to help households across the income spectrum.[22] In fact, this creates a cumulative effect of unnecessary cost burdens that can be addressed by another institutional arrangement.

Knowledge and Innovation

When the precautionary principle is adopted for all risks, even small-probability risks, the resulting regulation can be economically costly and informationally challenging. When chemicals are included on a "chemicals of concern list" or when other policy approaches attempt to apply the precautionary principle, producers and consumers are more likely to completely steer clear of the listed chemicals, consumers to avoid exposure to the now suspect chemicals, and producers to avoid exposure to consumer backlash or potential future regulatory sanctions. These can include fines, additional review of other product uses, bans on sales, and a host of requirements for additional testing to demonstrate that there is no negative effect of the chemical.

As a result, chemical use is curtailed simply because the chemical is listed and not necessarily because there is clear scientific evidence and empirical assessment of the risk. This can lead to a significant reduction in experimentation and innovation, the potential benefits of which are foregone. Additionally, the resulting limited use has important consequences for information discovery regarding the actual risks associated with the chemical. Because fewer opportunities will be available to validate the concerns empirically, the concerns underlying the decision to list a substance as a chemical of concern will remain unverified.

Political Pressures

All three approaches for managing risks associated with chemical use—the precautionary principle, cost-benefit analysis, and litigation—are subject to different degrees of political pressure. The use of fear-mongering and hyperbole by advocacy groups and pressure from chemical trade associations pressure the legislature and regulatory bodies to impose rules that favor their politically preferred outcome. Similarly, producers may lobby regulators to limit the handling of certain chemicals in order to raise barriers to entry or specifically disadvantage competitors that are significant users of the chemical in question. Sweeping regulatory reforms for chemicals spur a notable increase in contributions from special interests, which begs the question of whether the regulatory reforms are founded on scientific objectivity.[23] Industry has provided a large number of studies regarding the effects of chemicals in response to particular regulatory requests, often with the aim of demonstrating that the potential risk that has been identified can be eliminated. As a result, regulatory assessments of the risks associated

with chemical use become systematically more conservative and lean toward what is politically feasible, to the detriment of consumers, suppliers, and society at large. This reality highlights that calls for basing regulatory decisions solely on "science" fail to acknowledge the political nature of the regulatory process and how science, even "good" science, can be co-opted to support political goals.

While the goal of both regulatory approaches and lists of chemicals of concern is to reduce risk ex-ante, these mechanisms are problematic and are subject to capture by entrenched firms. For example, the decision to ban creosote in New York State ended up as little more than political theater. Anti-pesticide groups argued, based on limited evidence, that there were increased health risks associated with exposure to the chemical compound. Creosote, a popular wood preservative and antiseptic, was and still is an important component in US infrastructure, including railways, bridges, and marine highways. The resulting policy action was both precautionary, with little clear evidence of harm having occurred, and largely captured by the existing users of creosote in wood preservation. As a result, the final policy exempted most existing uses of creosote and eliminated only the uses for creosote that were not part of the entrenched interests. Those arguing for a ban claimed a huge win for the protection of human health despite seemingly little improvement. Further, the resulting policy has left New York with the discretion to make future exceptions.[24]

The creosote policy discussion highlights one of the benefits of a common law approach. Litigation could establish an incentive structure that is predicated on localized knowledge aggregated from previous cases and adjudicate the size and scope of the harm alongside the responsibility; however, the harm must be realized before action can be taken.

POLICY RESPONSIVENESS OF COMMON LAW

Regulatory requirements or standard risk allowances often are based on the experiences of "extra-sensitive individuals;" common law approaches assert "reasonable person" standards (i.e., the expectation that individuals act "with the same degree of care, knowledge, experience, fair-mindedness, and awareness of the law that the community would expect of a hypothetical reasonable person").[25] As a result, the common law usually incentivizes the development of a more flexible regulatory regime that considers the circumstances of time and place, or the local knowledge, to address potential harm. For established dangerous activities, strict liability may provide better outcomes, even in the face of uncertainty. Instead of limiting the use of particular chemicals ex-ante, such an ex-post approach may be better suited for aligning incentives, addressing uncertainty, and handling low-probability harms. Chemical manufacturers, by taking on financial responsibility for harms done, may be required to obtain liability insurance that covers more than just product defects but also harm from handling a chemical contained in the product. Without the use of regulations, the costs of safeguarding consumers could be internalized by the market for insurance. Common law processes take the administrative pressure from the public regulatory bodies and shift risk assessment and control into a private, competitive market. The resulting market would almost certainly require strong scientific analysis of the potential risks posed for those who bear the risk to correctly understand that risk and the corresponding liability they might face.

A strict liability rule would provide stronger incentives for producers to minimize the risk to the exposed population. Producers who are in any way using "chemicals of concern" or chemicals that pose a risk to consumers are automatically financially responsible for any damage caused

by the use of particular chemicals in their products. The reason for subjecting producers to that standard is that they are better able than consumers to estimate the risk involved with the chemicals included in their products and are equipped to take precautions against the risks. If the product has a large consumer base, the cost of liability could be spread more effectively across purchasers by raising the price to cover the cost of liability insurance, or to mitigate the risk through the use of alternatives.

Relying on strict liability forces the person or company producing and marketing the product to consider the accident costs associated with the product. Regarding potentially harmful chemicals, several iterations of risk assessments would continue. Advocacy groups can continue to perform their role, though scientific evidence would not only have to be accredited, but actual harm would have to be done. By incorporating the accident costs, prices would reflect the true cost of the product. The concern with chemical risk, or any risk in general, is that perhaps the price is not taking into account the social cost of producing the particular product. The social cost could be cancer treatments, environmental damages, and so forth. Strict liability would encourage producers to manufacture only those chemicals that yield more benefits than risks and to discontinue the manufacture of needlessly risky chemicals.

ILLUSTRATIVE CASE STUDIES

Flame-retardant chemicals

Flame retardant chemicals (FRCs) used in furniture upholstery, electrical casing, clothing, and other textiles to reduce the risk of fire have come under scrutiny in 33 states, including attempts to ban them.[26] Some states have already banned FRCs based on claims that they "have been shown to cause neurological damage, hormone disruption, and cancer." Organized advocacy groups have used the precautionary principle to push for these chemicals to be banned. This advocacy is not, however, based on credible science that clearly establishes the risk of harm. In fact, a study prepared by the Committee on Toxicology assembled by the National Academy of Sciences' National Research Council reports that "for most of the 16 candidate FR[C]s, the hazard indices for non-carcinogenic effects are less than 1 for all three routes of exposure." While some risk assessments of FRCs found that the carcinogenic risk might exceed the recommended levels, "the subcommittee believes that actual carcinogenic risk is likely to be much lower because of the extremely conservative (high) exposure estimates." The subcommittee clearly notes in its report that overestimating risks can result in adverse effects on public health if the FRCs are doing what they are meant to do, which is to reduce deaths and injuries from fires.[27]

One study that has been used to bolster claims of harm by advocacy groups found that the concentrations of organophosphate flame retardants in urine samples increased by a multiple of 16.5 from 2002 to 2015.[28] While that estimate may seem like a dramatic increase, it is not a significant departure from the baseline. The study measures the concentration of organophosphate flame retardants in nanograms per milliliter. The increase it found is roughly equivalent to the levels of arsenic we ingest through the air or tap water, which are extremely low.

Moreover, PFR exposure most likely increased as a result of the ban on the popular flame retardant pentaBDE, which led to a rise in organophosphate flame retardant use. The study concludes that the concentrations have risen in the sample population but that "additional data are urgently needed to determine whether levels of exposure experienced by the general population are related to adverse health outcomes."[29]

Despite this reality, Consumer Reports summarized the findings and concluded: "Not all flame retardants are harmful, but some, including organophosphates, are known to cause

adverse health effects, with human and animal studies linking them to cancer, hormonal changes, and fertility problems."[30] Despite the intimation that tests have been performed on humans, no such trials have occurred to determine adverse health effects.[31] Tests of conservatively high concentrations have been performed only on animals such as mice. No scientific conclusion has been reached, yet the lack of evidence has not stopped advocacy groups from making strong assertions and demanding a regulatory response based on the precautionary principle. If the risks are eventually demonstrated clearly, producers would ignore that reality at their own peril. Under a common law approach responsibility for understanding the risks rests with the producer, and producers who ignore scientific evidence about those risks would incur the liability of the harm caused. The risk surrounding FRCs would be better served by applying the common law approaches suggested in this brief, which account for risk of harm and the benefit of consumers. Responsibility for real harm caused by FRC use could be clearly assigned, and the incentives for the future development and use of FRCs would be better aligned.

Ethylene Oxide (EO)

Ethylene oxide (EO) is used in various personal care products, plastics, and household cleaners. Notably, it is used to sterilize more than 20 billion medical products in the United States.[32] In addition, EO is found naturally in the human body. An ongoing controversy around the use of EO in consumer products has developed, leading the Environmental Protection Agency to produce a study of those potential risks.

The EPA's Integrated Risk Information System (IRIS) program produced an assessment of EO carcinogenicity in 2016.[33] That report is being used to justify significant regulatory rulemakings and other regulatory actions, such as the National Air Toxics Assessment (NATA). The report, which uses a "unit risk estimate" that "corresponds to a one-in-a million increased cancer risk concentration of 0.1 parts per trillion, to calculate the EO risk," has been used to push precautionary approaches to EO use regulation.[34]

These demands are premised on the assessment's claims concerning cancer risk as a result of exposure to EO. However, the assessment relies on incredibly small amounts of exposure—exposure levels which are difficult to distinguish from levels of EO found naturally in the human body, exposure of EO outside of the body, and other chemicals with which subjects are interacting. In fact, this number is a "reference dose" intended to be used as a guideline for setting regulations, not to be the actual safety standard. The claims made range from a 3 percent increased risk for lymphoid cancers to a 15 percent increased risk for breast cancer.[35]

After the NATA office released a report on emissions data collected and estimated for 2014, the EPA generated a panic for communities near equipment sterilization plants that use EO. States and localities acted by shutting down medical sterilization plants, putting people out of work and patients at risk from unsterilized medical equipment. As the EPA attempts to offer alternatives for EO, shortages of sterile medical supplies continue, along with more infections and related deaths in hospitals.[36]

The risk of harm from ethylene oxide could be well-managed with the common law approaches suggested in this brief, allowing risk of harm and the benefit of consumers to be better accounted for. Responsibility for real harm caused by EO use could be clearly assigned, and the incentives for the future development and use of EO would be better aligned without eliminating the clear benefits of EO in sterilization and other uses.

Chlorine in Drinking Water

Chlorinated water has been a standard approach to ensuring clean potable water since the early 20th century, and chlorinated water systems have largely eliminated the presence of cholera,

dysentery, and other waterborne diseases where they have been widely used (Logsdon 2004).[37] Despite this history, point-of-use and home water treatment to remove chlorine has increased dramatically. This increase is often in response to marketing claims that suggest chlorine in water is linked to human cancers.[38] Those who push this belief often focus on a 40-year old study sponsored by the US Council of Environmental Quality, which states, "Cancer risk among people drinking chlorinated water is 93 percent higher than among those whose water does not contain chlorine."

That study, however, does not demonstrate causality between chlorinated water and the increased cancer risk. Studies conducted since that time have found either no correlation or generally small increases to the overall cancer risk, particularly bladder cancers. Furthermore, the mechanism by which the increased risk may be occurring is not well understood and has not been clearly established.

The Water Quality and Health Council, along with many other public health and advocacy organizations, have noted drinking water chlorination to be one of the greatest public health achievements. Unfortunately, demands to eliminate chlorine-based disinfectants from drinking water have increased and continue to gain traction. In 1992, Peru experienced an outbreak of cholera as a result of contaminated drinking water. Prior to the outbreak, the Pan American Health Organization was tasked to inform and recommend chlorination of the water supply as a way to disinfect public water systems in Latin American countries. However, PAHO officials were "encountering pockets of resistance to chlorination" by Latin American health officials. Because of the alleged risk of chlorine, officials held off on implementing the disinfectant programs. The well-intentioned precautionary stances by the government contributed to an additional 400,000 cases of cholera and more than 3,100 deaths.[39] Chlorine continues to stir fear as a "chemical of concern" for both developing and developed countries around the world.

CONCLUSION

Ex-ante approaches to chemical hazard regulation such as precautionary regulation and cost-benefit analyses face significant issues in their attempt to reduce risk surrounding chemical use. Precautionary regulation focuses exclusively on the risk of harm from the use of chemicals while ignoring the unseen costs to consumers and risk of harm that can occur from banning chemical use. Similarly, cost-benefit analyses can be politically captured to achieve the same result as precautionary regulation, although when well applied, and the full costs and benefits are considered are preferable to a fully precautionary approach as they allow the benefits of the chemical use to be considered in the regulatory process. The reality of political capture, however, has become especially salient as chemicals-of-concern lists become increasingly prevalent in both some US states and Canada. These lists, which have the potential to push systems that rely on cost-benefit analyses in the management of risk in the policymaking process towards precautionary approaches, are particularly problematic because they may inappropriately list substances where the scientific consensus is incomplete or nonexistent. Crafting lists that purport to cover chemical use risks may also create a false impression that non-inclusion on a list is an endorsement of a chemical's safety.[40] Further, the conversation regarding regulation of chemical use must account for the different concerns relating to institutional design. The precautionary principle, as the most stringent ex-ante form of regulatory intervention, comes with serious economic and health consequences that cannot be ignored. As states move in the direction of the precautionary principle by creating "chemicals of concern" lists, the costs and potential benefits of different institutional structures for managing chemical use risk ought to be considered.

When a precautionary approach is adopted

in response to relatively small increased risks, regulators have the potential to cause far greater harm than the documented risks illustrate. Because the mechanism causing the small increase is not well-understood, further research into that mechanism might yield mitigation strategies that would allow for improved safety. Precautionary regulation removes incentives for further research and has the potential to cause significant harm.[41] Again, even in the face of demonstrated harm, common law approaches are likely to yield at least equivalent and often better results than precautionary regulation.

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NOTES

[1] See Diana W. Thomas, 2019, "Regressive Effects of Regulation," *Public Choice* 180, no. 1 (July): 1-10; Randall Lutter, John F. Morrall III, and W. Kip Viscusi, 1999, "The Cost-Per-Life-Saved Cutoff for Safety Enhancing Regulations," *Economic Inquiry* 37 no. 4, (July): 599-608; and James Broughel, 2017, *Regulation and Economic Growth: Applying Economic Theory to Public Policy*. Fairfax: Mercatus Center.

[2] James Broughel and W. Kip Viscusi, 2017, "Death by Regulation: How Regulations Can Increase Mortality Risk." Vanderbilt Law Research Paper No. 18-31. Available at SSRN: https://ssrn.com/abstract=3169605.

[3] See Cass R. Sunstein and Robert Walmsley, 2005, *Laws of Fear: Beyond the Precautionary Principle*. New York: Cambridge University Press, 19.

[4] Steffen Foss Hansen, Lars Carlsen, and Joel A. Tickner, 2007, "Chemicals Regulation and Precaution: Does REACH Really Incorporate the Precautionary Principle." *Environmental Science and Policy* 10, no. 5 (August): 395-404.

[5] Sunstein and Walmsley, *Laws of Fear*, 19.

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