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Risk Perception and Drug Safety Evaluation

Abstract
The authors present a Risk communication framework based on a survey of empirical research concerning public Risk perceptions. They also apply it to the area of pharmaceutical regulation to suggest more effective regulatory strategies.

Keywords
communication, public, Risk, analysis, expert, regulations, policy
Risk Perception and Drug Safety Evaluation*

Ilan B. Vertinsky and Donald A. Wehrung**

Introduction

Do regulators need to concern themselves with public risk perceptions? Would the scarce social resources dedicated to the pursuit of safety not be more usefully deployed in improving the scientific basis of regulation?¹ These questions are asked repeatedly by professional risk assessors who must use significant resources to defend their actions (or inactions) and explain delays in the regulatory decision process. The prevalent view among risk assessors is that groups with distorted information and lack of understanding are subject to unreasonable fears. Regulators are frustrated because providing accurate information rarely satisfies public complaints. Indeed, in attempts to be open, objective and accurate, scientists often create suspicions and complaints of

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¹ Johnson, Risk Perception and Drug Safety Evaluation in Canadian Regulatory Agencies, presentation to Ottawa Workshop, supra.

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indifference to safety. They are continuously forced to defend their own integrity and the risk assessment process.

Basing risk judgments on objective scientific evidence using the standard risk analysis paradigm fails to consider the subjective elements of risk perception. It is therefore important for decision makers to be aware of public concern for health risks in order that risk management decisions properly reflect such concern and ultimately receive public acceptance.  

In this paper we present a framework which articulates the linkages between public risk perceptions and the regulatory process. The paper explores alternative types of communication strategies and their role in improving public safety because risk communications can be a vital factor in managing such linkages. In the last section of the paper the framework is employed to analyze communication strategies in drug safety evaluation.

Why Knowledge of Risk Perceptions Is Important

There are several reasons why government regulators charged with the promotion and protection of health need to know about the risk perceptions of different groups in our society and how they develop and change. These reasons are discussed below.

- Risk perceptions can influence the public policy agenda concerning the allocation of resources and regulations to reduce risks.

Since risk is ubiquitous, paying attention and evaluating all potential risks is bound to stop all productive activities. Fears become a major social force in determining the political agenda.  

Risk perceptions are formed both by direct experience and from the words and deeds of


3 Somers, Introductory Remarks to Conference on Risk Perception and Drug Safety Evaluation, presentation to Ottawa Workshop, supra.
influential others. The perceived riskiness of various hazards is often at variance with scientific judgment about risks. Thus, attention to public fears may mold a public policy agenda which focuses on some highly feared, but improbable, dangers to society rather than less feared, but more likely hazards. "Policy directed primarily at alleviating public anxieties can result in large expenditures having low cost effectiveness. Conversely, serious risks may also be neglected due to public indifference."

- Risk perceptions can influence market processes. When perceptions reflect lack of information, there is "market failure," i.e., loss of social welfare.

Perceptions influence what people buy, so unjustified fears or misplaced over-confidence by consumers may lead to serious economic distortions. That is, when individuals make decisions, the underlying benefits and costs they consider in choosing among alternative options may not correspond to the true consequences of these options. For example, patients may avoid using certain medications or procedures because of misplaced fears, thus increasing the risks to which they are exposed. Alternatively, patients may gravitate toward medications and procedures that appear safer than they are. The major justification for regulatory action in market economies is market failure. The regulator may be forced to intervene in market processes to improve individual choices and prevent serious dislocations of market processes resulting from unjustified public fears.

- Risk perceptions can influence individual behaviour and contribute to or detract from risk management efforts.

6 Supra note 2, at 203.
Since exposure to risk depends in part on the behaviour of individuals (e.g., compliance behaviour), and, since risk perceptions motivate "safety oriented" behaviour, such perceptions determine the effectiveness of different protection programs. For example, patients typically do not guard childrens’ access to medication in a sufficiently careful manner (e.g., through locked medicine cabinets) because they underestimate the risks. This knowledge may indicate that certain types of packaging designs for drugs are especially dangerous for children.\(^7\) Similarly, if the regulator expects patients to feel invulnerable to taking excess medication, he may restrict availability of prescription and over-the-counter medications.

To modify peoples’ behaviour, one must understand the way they think about risks in different social contexts\(^8\) and the way such thinking leads to decisions, actions and responses to risk communications.\(^9\) The role that a person plays (e.g., voter, member of an interest group, patient, family member, regulator) is triggered by a situation and by the social and historical context in which a risk is presented. These factors affect how (and whether) a person thinks about risk, what risk values are considered and how attitudes and risk perceptions are structured. Attempts to modify behaviour must be informed by detailed knowledge of how a person thinks about risks and how new information is likely to be processed. Expert intuition is no substitute for experience. A risk communication that is not understood and fails to motivate the desired behaviour cannot be considered

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\(^8\) Whyte, *Studies of Risk Perception in Canada*, presentation to Ottawa Workshop, supra.

\(^9\) Gregory, *Current Research Directions in Risk Perception in the United States*, presentation to Ottawa Workshop, supra.
successful, no matter how highly it is rated by its own creators.10

- Risk perceptions can affect how new risk evidence is evaluated.

Risk perceptions constitute a filter for attending to and interpreting new data and information.11 This is true not only for citizens at large, but also for experts and politicians. Indeed the regulatory process itself may experience distortions in communications and risk assessments. For example, Philbrook12 observed that few spontaneous adverse reactions to drugs are reported by physicians whose assessments are biased by their prior risk perceptions. This behaviour reduces opportunities for learning. Knowledge of risk perceptions may be used to improve communications in the regulatory process and to ensure proper learning over time.

- Risk perceptions can affect views of the integrity of the regulatory process and trust in risk assessors.

Since trust and confidence are major factors in reducing unfounded fears, it is important to enhance the perceived integrity of the regulatory process. The dissonance created by disconfirming evidence may be resolved by reducing the confidence in the data and in both the process and experts which generated it.13 Understanding the dynamics of risk perception is fundamental to the design of risk communication strategies that do not threaten the perceived integrity of the regulatory and risk management process. Failure to protect the perceived integrity of the process will inevitably amplify public risk perceptions.

As we have indicated, "risk perception" is a key variable that permeates risk policy and risk management processes, including **initiation, risk identification, risk estimation, risk evaluation, risk**

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10 *Id.*
12 *Industry Perspectives*, presentation to Ottawa Workshop, *supra*.
13 *Supra* note 11.
reduction and risk control phases.\textsuperscript{14}

Table 1
The Risk Policy/Management Process (OECD 1983)

<table>
<thead>
<tr>
<th>Phase</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation</td>
<td>Begin process in response to, or in anticipation of, a perceived problem.</td>
</tr>
<tr>
<td>Risk Identification</td>
<td>Observe and recognize new risk parameters, new relationships among existing parameters, or perceived changes in the magnitude of existing parameters.</td>
</tr>
<tr>
<td>Risk Estimation</td>
<td>Quantify the probabilities and consequence values for an identified risk.</td>
</tr>
<tr>
<td>Risk Evaluation</td>
<td>Define acceptable levels of risk to individuals or society. Includes identifying adverse consequences and relating exposure to consequences.</td>
</tr>
<tr>
<td>Risk Reduction</td>
<td>Lower the probability of occurrence and/or the value of a risk consequence, thereby reducing the magnitude of risk.</td>
</tr>
<tr>
<td>Risk Control</td>
<td>Determine whether risk reduction efforts have succeeded.</td>
</tr>
</tbody>
</table>

Table 1 summarizes these phases. In each phase, however, different aspects of risk perception and its formation may be dominant, and different aspects of research may inform risk regulators and managers.

**Risk Perception in the Policy/Management Process**

Figure 1, below, identifies the major pathways through which risk perceptions play a key role in shaping the regulatory process.

\textsuperscript{14} ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, PRODUCT SAFETY: RISK MANAGEMENT AND COST-BENEFIT ANALYSIS (1983).
Figure 1 provides a schematic view of the principal direct and indirect modes through which risk perceptions enter or affect the
indirect modes through which risk perceptions enter or affect the regulatory process. We distinguish two basic types of risk perceptions: (a) those which are held by groups as integrated judgments of riskiness of options and their acceptability and (b) those which relate solely to facts (i.e., mainly probability estimates for consequence values). The discord alluded to in the introduction to this paper between the risk perceptions of professional risk assessors and the perceptions of laypeople occurs mainly in the domain of integrated riskiness judgments. Experts tend to form such judgments by combining probabilities and some simple quantitative expressions of consequences (mainly fatality rates). Laypeople, on the other hand, tend to focus more on consequences described by multiple attributes that relate not only to the final outcomes of a hazard but also to the context of exposure. These judgments tend to discount the importance of probability in determining riskiness and acceptability of risky options. Thus the discord has two dimensions, one based on factual concerns and the other on social values. On questions of facts concerning likelihood and consequences the assessor can legitimately point to his superior information, understanding and analysis relative to the lay public. On questions of values and preferences, however, the public is sovereign.

Ideally the regulatory process should improve public knowledge of facts and analysis, so that choices reflect public preferences that are informed and well thought out. This is what we call informed consent. Alternatively, the regulator should glean from risk perceptions the values held by the public in order to make policy choices on their behalf in accordance with these values. This process can be referred to as imputed informed consent since the regulator chooses as the public would have chosen had it been in possession of appropriate knowledge. Dismissing public risk perceptions as a drag on the regulatory process is

\[^{15}\text{Coppock, The NRC Project on Risk Perception and Communication, presentation to Ottawa Workshop, supra.}\]
both unjustifiable and imprudent. Ignoring perceptual biases in the judgments of experts is often a cause of lower quality “safety” decisions.

However, Lichtenstein et al.\textsuperscript{16} caution regulators to recognize that public preferences are often inconsistent and inadequately developed. Moreover, people do not always want what they say they want, and the public is sometimes misinformed about key aspects of a potential hazard. Therefore regulators and other social decision makers are urged to have a backbone, able to go against (while never ignoring) public desires, and a heart, caring for and respecting (but not always acquiescing to) public views.\textsuperscript{17}

\textit{The Initiation and Risk Identification Phase}

The regulatory agenda is determined in the initiation and risk identification phase. Part of the agenda emerges routinely from ongoing work of the regulatory agency and its formal responsibilities (e.g., monitoring and reporting systems). Part of it is determined by scientific priorities (formal choice of candidates for risk assessments). Also, an increasing part of it is determined by public complaints and the influence of a variety of interest groups. Clark has observed, for example that:\textsuperscript{18}

While American drug regulators and risk assessors are being condemned as overly conservative by collective social welfare studies... powerful, articulate, and convincing consumer groups are simultaneously attacking them for “caving in to industry” and neglecting their responsibility to assure the public’s safety.

He concludes that:\textsuperscript{19}

\begin{itemize}
\item \textsuperscript{16} \textit{When Lives are in Your Hands: Dilemmas of the Societal Decision Maker} 24 (1989) (Working paper available from Decision Research, Eugene, Oregon).
\item \textsuperscript{17} \textit{Id.} at 24.
\item \textsuperscript{19} \textit{Id.}
\end{itemize}
For better or worse, public safety is now and is likely to remain a primarily political issue. Scientific data and economic analyses — even of the inordinately high quality encountered in the drug field — are simply not going to be the central issue in even the most technical of risk decisions.

In Canada, perhaps because of its consensus oriented culture and consultative style of risk handling,\textsuperscript{20} health risks are perceived as important individual problems rather than as an important part of the public agenda.\textsuperscript{21} However, spill-over through the American mass media and through economic and institutional linkages is likely to internalize safety issues raised in the U.S. and mold the agenda.

The nature of fear is asymmetrical — it is easier to prevent fear than to reassure people who are afraid.\textsuperscript{22} This means that preventative measures to “inoculate” Canadian risk perceptions by appropriate communications (e.g., demystifying risks, reducing surprises) may protect the public agenda from myopic hysteria or manipulation by groups with hidden agendas. Risk communications can raise the understanding of issues or actions and are successful if the public believes that it is adequately informed. It is unrealistic, however, to expect that risk communications will necessarily reduce conflict and reassure the public.\textsuperscript{23}

"Knowledge of the technical, scientific, and medical aspects of hazards tends to be low amongst the population at large, but is generally higher for males, younger adults, and better educated individuals."\textsuperscript{24}

\textsuperscript{20} Thompson, \textit{To Hell with Turkeys! A Diatribe Directed at the Pernicious Trepidity of the Current Intellectual Debate on Risk}, in \textit{VALUES AT RISK} 113 (D. MacLean ed. 1986).


\textsuperscript{23} \textit{Supra} note 15.

\textsuperscript{24} \textit{Supra} note 2, at 191.
However, knowledge does not seem to be correlated with either risk attitude or perception.\textsuperscript{25} The degree to which risk communications are reassuring is a function of the attributes of their source (e.g., legitimacy) and quality (e.g., accuracy).\textsuperscript{26} The congruence of the communicated message with commonly held risk perceptions is a major determinant in the selective attention and retention of the communication by the public. Thus, knowledge of risk perception is vital for effective management of the regulatory process. A major source of information concerning risk perception and the regulatory agenda in Canada is public survey data. The major problem is that "only when problems are already 'issues' do surveys begin to collect data on the public's perception of them."\textsuperscript{27}

To anticipate the public response to new hazards or new responses to existing hazards, one must discover what people mean when they say that something is (or is not) risky and determine what factors underlie these perceptions.\textsuperscript{28} The psychometric paradigm that has been developed mainly by researchers at Decision Research (Eugene, Oregon) and various collaborators attempts to understand how judgments of the riskiness of hazardous activities, substances and technologies are related to certain attributes of these risks. These include:\textsuperscript{29}

(i) the hazard's status on characteristics that have been hypothesized to account for risk perceptions and attitudes (e.g., voluntariness, dread, knowledge, controllability); (ii) the benefits that each hazard provides to society; (iii) the number of deaths caused by the hazard in an average year; (iv) the number of deaths caused by the hazard in a disastrous year; and (v) the seriousness of each death from a

\textsuperscript{25} Supra note 21.
\textsuperscript{26} Supra note 15.
\textsuperscript{27} Supra note 21, at 49.
\textsuperscript{28} Slovic, Fischhoff & Lichtenstein, \textit{Why Study Risk Perception?} 2 RISK ANALYSIS 83 (1982).
\textsuperscript{29} Id. at 84-85.
particular hazard relative to a death due to other causes.

These research efforts consistently confirm that perceived risk is a multidimensional concept and that only one of those dimensions corresponds roughly with a formal definition of risk in the sense of rates of fatalities or injuries.\textsuperscript{30}

Using psychometric scaling and multivariate analysis techniques, the Decision Research group\textsuperscript{31} concluded that the riskiness judgment of a hazard is primarily a function of what they defined as (1) "dread risk," i.e., perceived lack of control, dread, catastrophic potential, fatal consequences and the inequitable distribution of risks and benefits, and (2) "unknown risk," i.e., the degree to which hazards are not observable, unknown, new and delayed in their manifestation of harm. A third component of some studies was the number of people exposed to the hazard.

Vlek and Stallen\textsuperscript{32} used an alternative psychometric method to characterize risk judgments. Their study identified two factors: (1) the size of a potential accident and (2) the degree of organized safety.

Von Winterfeldt, John and Borcherding\textsuperscript{33} tested the accuracy of perceptions of fatality risks and concluded that: "fatality probability operates as a primary determinant for intuitive risk judgments; if that probability is relatively low, and the potential for large scale accidents increases, disaster potential begins to shape risk judgments." The study indicates that in a focused public policy debate on acceptable risk where the potential for large scale disaster is not large, experts and laypersons may form judgments of risks in a similar way, i.e., on the basis of

\textsuperscript{32} \textit{Judging Risks and Benefits in the Small and in the Large}, 28 \textit{ORGANIZATIONAL BEHAVIOUR AND HUMAN PERFORMANCE} 235 (1981).
\textsuperscript{33} \textit{Cognitive Components of Risk Ratings}, 1 \textit{RISK ANALYSIS} 286 (1981).
fatality rates. In such cases the provision of information may reduce the gap in risk perception.

Clearly, an understanding of the role of risk perception in shaping the political agenda requires consideration of the ways in which interest groups can heighten and manipulate fears or draw public attention to hidden, but important, hazards. It is necessary to consider how public institutions (e.g., courts) and processes (e.g., legal proceedings) define, mold and legitimize risk perceptions, attitudes and responses to risks. One must also consider the impact of accidents upon risk perceptions and the role of such experiences in transforming latent perceptions and fears into actions (e.g., complaints, political activity, etc.).

The impact that interest groups can have in amplifying and mobilizing risk perceptions is well documented. The impact is larger when technical experts disagree, when such disagreement is public, and when the types of risks are those which rate high on the "dread" and "unknown" risk dimensions. Their impact is also large if the constraints they seek to impose do not appear to interfere immediately with established patterns of behaviour and life styles.

The role of accidents in shaping the policy agenda has been a subject for psychometric research. An important concept that has emerged from this research is that the seriousness and higher order impacts of an accident are determined in part by what the event signals.

Slovic has gone on to say that:

An accident that takes many lives may produce relatively little social disturbance (beyond that experienced by the victims' families and friends) if it occurs as part of a familiar and well-understood system (such as a train wreck).

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34 See, e.g., M. DOUGLAS & A. WILDAVSKY, supra note 4 and SOCIAL AND CULTURAL CONSTRUCTION OF RISK (B. Johnson & V. Covello eds. 1987).
35 Supra note 4.
37 Supra note 31, at 284.
However, a small accident in an unfamiliar system (or one perceived as poorly understood)... may have immense social consequences if it is perceived as a harbinger of further and possibly catastrophic mishaps.

Kasperson et al. recently developed a conceptual framework that links the technical assessment of risk with psychological, sociological and cultural perspectives of risk perception and risk-related behaviour. They describe a process for the social amplification of risk. This process involves two major stages — the transfer of information about the risk or risk event and the response mechanisms triggered in society.

Much remains to be understood about how risk perceptions are amplified by social processes. However, evidence exists with respect to the following: (1) Experience with dramatic accidents or risk events increases the memorability and imaginability of the hazard, thereby heightening the perception of risk. (2) Large volumes of information about an event may serve as risk amplifiers (e.g., mass media coverage). (3) Disputes among various stakeholders or risk assessors amplify risk perceptions. (4) Reports which explain risks and the underlying processes that generate them in simple terms attenuate risk perceptions.

The Risk Estimation Phase

Risk estimation is the process of quantifying the probabilities and consequence values for identified risks. Experiments show that a variety of cognitive biases affect the processing of risk information into
perceptions concerning probabilities of risky outcomes. People have many shortcomings in acting as an “intuitive statisticians.” Because of their limited cognitive abilities, almost all people employ heuristics and simplifications in processing information. These mechanisms, as well as the processes of selective attention and retention of information, serve people well in many situations, but may bias risk assessment.

Tversky and Kahneman have identified three major types of heuristic mechanisms that even experts tend to use when assessing probabilities — representativeness, availability, and anchoring and adjustment.

The first mechanism involves the use of “stereotypes” or representative images of the conditions associated with an event. When people assess the probability of the event, they attempt to judge the similarity of the assessed circumstances to the “ideal” representation of the event. Therefore, they tend to arrive at a probability as a function of the similarity or dissimilarity between these circumstances and the ideal representation. Shear provided examples of physicians who judge adverse drug reactions on the basis of superficial similarity in symptom patterns, thus ignoring key diagnostic clues in the medical history of the patient and his family.

This representativeness heuristic leads to the following threats to the validity of probability assessments:

48 Shear, Clinical Perspectives, presentation to Ottawa Workshop, supra.

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• *Ignoring base-rate probabilities.* Differences in frequencies of an event in a population should be reflected in judgments unless there is compelling evidence that the event assessed is unique. Experimental evidence suggests that such statistical information is usually ignored when subjects are provided with specific detailed information.

• *Ignoring sample sizes.* Large random samples, by virtue of the law of large numbers, are similar in character to the population from which they were drawn. However, small samples do not have this property. Yet, people tend to make strong inferences about the population at large from small samples. For example, Shear\(^50\) reports that clinicians make strong diagnoses about rare conditions even though the sample of patients that they could possibly observe is too small on which to base any general inference.

• *Ignoring predictability.* The representativeness heuristic tends to reduce an assessor’s inclination to examine critically the predictive validity of the information at hand. Thus people tend to associate less risk with an event or action that is favorably described and to associate more risk with one described less favorably. This occurs despite the fact that the degree to which the description is favorable is unaffected by the reliability of the description or by the degree to which it permits accurate prediction.

• *Having illusions of validity.* Confidence about predictions should refer to the reliability and adequacy of data, not to the association it evokes about the similarity of the description to some stereotypical program.

• *Ignoring regression toward the mean.* One should expect performance significantly above the mean to regress to the mean in subsequent observations. Similarly, performance significantly below the

\(^{49}\) *Supra* note 46.

\(^{50}\) *Supra* note 48.
mean is more likely to improve. Assessors tend to ignore this because it is incompatible with the belief that the value of outcome variables should be as extreme as the value of input variables.\textsuperscript{51}

The second frequently used mechanism of probability assessment is called the \textit{availability heuristic}. It occurs when people relate the probability of an event to the ease with which they can imagine it happening, or the frequency with which they have encountered similar events in the past. The main problem with this is that the ease of imagining an event has much more to do with its salience and complexity than its frequency. Johnson\textsuperscript{52} pointed out that people can easily imagine the occurrence and consequences of cancer or malformation of fetuses, but they have difficulty with aplastic anemia or agranulocytosis. Thus the probability and consequences of the latter tend to be underestimated. Judgment using this heuristic is also influenced by the special training and experiences of the assessor.

Similarly, the frequency with which one remembers encountering an event depends on not only its objective frequency but also its salience. This mechanism is especially subject to bias because people selectively observe and recall events. Public perceptions, for example, are affected more by dramatic reports in the mass media (e.g., Three Mile Island or the Mississauga train derailment) than by well-documented scientific studies. A recent television presentation on Thalidomide victims did more to shape public perceptions than dissemination of details about extensive drug safety evaluation programs.\textsuperscript{53} Also, because recall tends to fade over time, the \textit{availability heuristic} results in a bias towards recent events.

The third heuristic of probability assessment is called \textit{anchoring and adjustment}. The process of eliciting probabilities typically starts with an

\textsuperscript{51} Supra note 46.
\textsuperscript{52} Supra note 1.
\textsuperscript{53} Supra note 12.
apparently reasonable initial value (called an "anchor"). Then, as pertinent information is acquired, the initial estimate is adjusted. There is substantial evidence that the degree of adjustment is insufficient and that the initial estimate (even if arbitrary) plays a significant role in the determination of a final estimate of the probability in question. By starting with different initial values, one can affect the final value elicited. A similar phenomenon reported by Edwards was the tendency of experts to be conservative when new information became available, i.e., they did not revise probabilities in accordance with the revision rates prescribed by Bayes theorem.

Psychologists have also noted other biases. (1) The mode of presenting data influences the assessment process. Vivid, interesting, qualitative data has more influence on the assessment than dull, quantitative data. (2) Context affects the perceived variability of outcomes. The assessment of the variability of a series of numbers is affected by the absolute size of the numbers. (3) There is a tendency to assign higher probabilities to events which please a person or their superiors. (4) Small probabilities are generally overestimated and large probabilities tend to be underestimated. (5) There is a tendency to overestimate the joint probability of independent events and to underestimate probabilities of disjunctive events. (6) Estimations of probability distributions tend to be too tight, i.e., the variance is underestimated. The assessment of extreme fractiles is particularly prone to bias.

55 *Supra* note 44.
While perceptual and cognitive biases may reduce the quality of risk estimation, the attributes of the process and the way its results are communicated may also affect risk perceptions adversely.

**The Risk Evaluation Phase**

"Risk evaluation is the complex process of defining acceptable levels of risk to individuals or society. It concerns what risks/injuries can be accepted having regard to risk groups, risk environment, etc." Public risk perceptions should be considered in the evaluation process both as a reflection of the need for anxiety reduction and as an important factor in determining the potential for "ripple effects."

As we have observed, professional risk assessors tend to discount qualitative attributes of risky situations and instead to focus on what they perceive as objective measures. By doing so, they forget that public concerns are a real social phenomenon that public safety programs can partially alleviate. Of course one may look for other means to deal with anxieties such as public education, but ignoring public anxieties or giving them little attention violates the basic tenet of consumer sovereignty. It also ignores that certain areas of safety are perceived by the public as the sole domain and responsibility of government (as opposed to other domains where individual safety behaviour is perceived to be indicated). The denial of public expectations may lead to the erosion of public trust in the regulatory process and eventual political intervention.

Perhaps more important is the threat of "ripple effects" that can unleash tidal waves. Some accidents that were not prevented can trigger higher-order consequences that are far more devastating than the damage of the accidents themselves. These potential higher-order impacts must

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60 *Supra* note 14, at 26.
be considered when evaluating the benefits of a safety program. It may be appropriate to allocate resources to prevent an accident even when the direct impacts of the accident are likely to be small and its probability low, if a single instance of the accident can trigger events which lead to a serious interruption of social processes and the functioning of social institutions. For example, it is in the interest of both government and pharmaceutical companies to prevent accidents or risks in over-the-counter markets that may lead to public hysteria and destruction of that market through excessive regulation or significant and undesirable changes in consumer patterns.

Another important phenomenon that can influence the quality of decisions in the risk evaluation phase is the framing effect which shows that one’s perceptions and judgments can be significantly influenced by the way in which issues are stated. Tversky and Kahneman\textsuperscript{61} have conducted a series of experiments which demonstrate the serious effects that problem framing can have on risk benefit judgments. It appears that decision makers will take risks to avoid a “sure loss,” but are conservative when “sure gains” are involved. By altering the reference system for defining a problem and formulating problems in terms of “gains” rather than “losses,” one evokes a conservative bias and vice-versa. The regulation of health, safety and the environment is especially vulnerable to these problems because framing choice options in terms of lives gained or lost magnifies this phenomenon. High emotional content and large uncertainty are fertile grounds for the rise of bias, manipulation and sharp disagreements.

Finally, another important bias occurs because low probability, but very harmful, risks tend to be judged by the public in terms of their consequences rather than their probabilities.\textsuperscript{62} In contrast, regulators

\textsuperscript{61} Tversky & Kahneman, \textit{The Framing of Decisions and the Psychology of Choice}, 211 \textsc{Science} 453 (1981).
tend to focus upon the expected values of consequences and discount the risks with very small probabilities.

**The Risk Reduction and Control Phase**

"Risk reduction is the action of lowering the probability of occurrence and/or the value of a risk consequence, thereby reducing the magnitude of the risk."\(^{63}\) The actions involved may range from tight regulatory constraints or prohibitions of certain technologies, products, behaviour, etc. to activities which enhance voluntary actions (e.g., informational and educational programs) or to nonaction. The choice among these options and their implementation is influenced by risk perception in several ways. Generally, "people respond to hazards they perceive. If their perceptions are faulty, efforts at public and environmental protection are likely to be misdirected."\(^{64}\)

Knowledge of risk perception is important in selecting an implementation strategy for reducing risk. Such a strategy might include programs to modify perceptions, to enhance individual safety behaviour, to alleviate fears so a regulatory program will be more acceptable, or to amplify risk so political support for a program can be mustered.

Specific perceptual problems must be dealt with at this stage. These include reconciling divergent opinions about risk among experts, regulators and laypeople, as well as improving knowledge of laypeople about safety-enhancing activities and risk management skills.

The risk reduction phase should include a control (or follow-up) phase where program implementation is monitored. The control phase should include activities to control and mitigate accidents and other risks as they occur. These activities must include both the dissemination of warning and emergency information and actions to contain unproductive

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\(^{63}\) *Supra* note 14, at 26.

\(^{64}\) *Supra* note 5, at 181.
ripple effects. Risk communication informed by an understanding of risk perceptions is key to any successful control strategy.

**Risk Communication**

We have emphasized the important effects that risk perceptions can have in molding regulatory risk reduction programs and determining their success. We have also stressed that the key control variable in modifying risk perceptions and influencing the degree to which risk perceptions trigger action is the communication pattern associated with the regulatory process. Covello, von Winterfeldt and Slovic observed that:

Risk communication takes place in a variety of forms, ranging from product warning labels on cigarette packages and saccharin bottles to interactions between officials and members of the public on such highly charged issues as Love Canal, AIDS, and the accident at Three Mile Island. Recent experience has shown that communicating scientific information about health and environmental risks can be exceedingly difficult and is often frustrating to those involved.

Typical problems involve complaints from regulators, industry and scientific experts that the public does not understand technical issues and that its perceptions are formed by irrational fears, biased media and the influence of groups with hidden agendas. The public often interprets government and industry inaction as lack of concern and interest. Risk messages are also often viewed as manipulative.

Covello, von Winterfeldt and Slovic reviewed the literature on efforts to communicate information about health and environmental

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risks. They suggested that communication problems arise from (a) message characteristics and problems (e.g., limitations of scientific assessments), (b) source characteristics and problems (e.g., limitations of risk communicators and risk assessment experts), (c) channel characteristics (e.g., limitations in the means or media by which scientific information about health or environmental risk is transmitted) and (d) receiver characteristics (e.g., characteristics of the intended recipient of the communication).

The directions to improve communications include the following:\textsuperscript{67}

1. Equip the public through education with basic knowledge and skills to understand scientific facts about risks (a long term strategy).
2. Relate the risk message simply and without complex technical terms.
3. Reduce public confrontation among technical experts, in particular the type of confrontation that is induced by adversarial processes.
5. Design communication messages that deal with the qualitative aspects of risk perceptions.
6. Avoid or counter balance media reporting that emphasizes drama.
7. Avoid over-simplifications and distortions.
8. Provide a balanced discussion of risks and benefits.
9. Provide guidance to action.

Underlying this approach is the idea that after informed debate, consumers tend to behave in ways which achieve socially optimal levels of safety. Thus individuals must be presented with relevant information in effective ways. Presenting information effectively requires making it available in the right place, at the right time and to the right audience. It

\textsuperscript{67} With regard to item 6, see Gunter and Wober, \textit{Television Viewing and Public Perceptions of Hazards to Life}, 3 J. ENVT. PSYCHOLOGY 325 (1983). Their evidence implies that the media has less effect in forming risk perceptions than is widely believed.
also requires that the message be interpreted correctly. Design of effective communication requires understanding the mental models used by people in analyzing risk and choosing actions.

MacGregor, for example, examined the effective use of warning labels. He observed:

For a warning to be effective, it must be noticed by the product user. The easier it is for an individual to gain access to the warning, for example, the greater the likelihood that it will be read.... Designing effective warnings, however, also requires attention to psychological factors associated with information processing and risk perception.

He points out that the language used in the warning should not be too complex:

A warning can also fail on language grounds if its choice of terms to express product risks are misunderstood. This can happen either because the context in which the warning is presented is ambiguous or because risk-related terms having a precise meaning to technical experts are interpreted more broadly by a lay audience.

The warning must fit into the individual’s knowledge structure (or mental model) associated with its domain because it is interpreted and coded within the existing knowledge structure.

An alternative communication strategy is one that aims to modify behaviour. The focus is on the “presentation format” for delivering information and effecting behavioural change. Kline and Leiss provided examples of strategies for designs of health hazard warnings

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69 INFERENCES ABOUT PRODUCT RISKS, supra.
70 Id. at 75.
71 Id. at 76.
72 Supra note 7.
which employ modern advertising and marketing techniques to modify behaviour. The effectiveness of a communication is seen as a function of modifying not only the information base and the cognitive processes of individuals but also their attitudes and values. They base their approach upon the conceptual work of Beltramini who identified two relevant categories for health advisory messages — information content and presentation format. The experimental approach that underlies the strategic choice of communications seeks to identify attitudinal and behavioural changes resulting from the assimilation of the alternative contents, forms and dissemination patterns of messages. The strategic choice is based on four elements: positioning, choice of a marketing concept, market segmentation and choice of an effective medium.

While the focus of many communication studies is on the flow of information from risk managers to the public, one must recognize that what the public feels about risk must also be communicated effectively to regulators. Risk communication is a two-way process. To be effective, it must ensure that the public has effective channels of communication to risk managers.

The Special Case of Risk Perception and Drug Regulation

“Pharmaceuticals have become common in everyday life, having advantages and disadvantages. Almost everybody uses drugs at one time or another, seeking the benefits and accepting the risks”.

Some drugs are freely available (i.e., over-the-counter), others can be readily prescribed by a physician and still others are further restricted. In all cases, risks are influenced by the behaviour of individuals as affected by

74 Supra note 9.
75 Jungerman, Schutz & Thuring, Mental Models in Risk Assessment: Informing People About Drugs, 8 RISK ANALYSIS 147 (1988).
their knowledge. In the over-the-counter market, information about risks is more difficult to disseminate because of the lack of precise targeting. Also, over-the-counter marketing itself suggests low risk.

The current process of regulating pharmaceuticals in Canada and the U.S. reflects public risk perceptions in an implicit rather than an explicit manner. In general, evaluation of new drugs at the U.S. Food and Drug Administration is consistent with the acceptance of greater risk for greater gain. If a new drug offers little potential advantage over existing drugs for an illness that is not life-threatening, but is relatively common, a fairly large data base would be needed to provide acceptable evidence of safety. On the other hand, if a new drug offers an important benefit for treatment of a serious illness, especially where there are no satisfactory drugs available, approval would require significantly less data. An important element in ensuring a credible system is openness, generally in the form of open advisory committee meetings with free discussion among scientists. Selection of knowledgeable and reputable scientists for advisory committees is vital to process quality, but even well qualified scientists need experience and training in the particulars of the scientific regulatory functions. Lack of experience and use of ad hoc committees can adversely affect the quality of decisions.\textsuperscript{76}

Lack of understanding by laypeople can lead to fears and pressures on regulatory agencies that hinder their efforts. Tight constraints do not necessarily mean more safety because many drug choices trade off risks along several dimensions to minimize total risk. Indeed, when some drugs are eliminated, less effective and riskier substitutes may take their place.\textsuperscript{77}

Prescribed drugs involve physicians as intermediaries. As a result, their use is affected by the relationship between patient and doctor and

\textsuperscript{76} Temple, \textit{Risk Perception and Drug Safety Evaluation in the United States}, presentation to Ottawa Workshop, \textit{supra}.

\textsuperscript{77} \textit{Supra} note 1.
the risk perception of doctor and patient (as influenced by the doctor).

Pharmaceuticals are usually purchased and consumed voluntarily, although those with more serious ailments may view their actions as not totally voluntary. The risks are typically immediate (e.g., side effects) and in many cases reversible if discovered. With prescription pharmaceuticals, patients typically accept the superior knowledge of the physician and delegate, in part, their decision-making authority. Thus, pharmaceuticals fall into a category of risks that involve lower "dread" and "unknown" characteristics but are susceptible to moderate ripple effects. These risks will be lower in situations involving prescription drugs and higher for unexplained risks in the over-the-counter market.

These observations have been confirmed by preliminary studies of risk perception of prescription drugs in both Canada\textsuperscript{78} and Sweden.\textsuperscript{79} In contrast to high risk perceptions generally associated with the use of other chemicals, no fears of prescription drugs were evident.

Prescription drugs, with the exception of sleeping pills and antidepressants, were perceived as rather high in benefit and low in risk. They appeared to be sharply differentiated from other chemicals and from illicit drugs. The concerns about sleeping pills and antidepressants perhaps can be traced to extensive media publicity during recent years regarding the risks of addiction and overdose from these and similar drugs.\textsuperscript{80}

However, pharmaceuticals were seen as sending a strong warning signal when adverse reactions did occur.

The Swedish study asked respondents how they viewed the risks of various hazards over time. Although most risks examined (e.g., chemicals, heart disease, cancer, climatic change and travel) were seen

\textsuperscript{78} HEALTH AND WELFARE CANADA, HEALTH RISK STUDY, PHASE II: NATIONAL SURVEY (1984).
\textsuperscript{80} Id. at 109.
as greater now than in the past, this was not true for prescription drugs.

The potential for ripple effects was evident in responses of survey participants to a report of a suspected, but not proven, link between a drug and some fatalities.

At a hint of trouble, 75% of those surveyed wanted the drug removed from the market. However, one of the most intriguing findings in this study was the indication that evidence of safety and efficacy, in combination with warning information, could reverse a high proportion of these initial demands for withdrawal of the drug. 81

This survey indicates that drug regulation may be less adversely affected by distorted public risk perceptions than other areas. This may be a result of the tight regulatory process and the evidence of safety in the drug industry. However, the increase in the market share of non-prescription drugs, the increased potential for accidents and the deterioration of patient-doctor relationships (resulting from heightened demand) suggest that the potential for ripple effects may increase.

The aspect of risk perception that currently dominates discussion concerns over-confidence in self medication and lack of confidence in instructions and warnings. Indeed, most empirical research on drug risk perceptions focuses upon the search for effective ways to disseminate information to improve patients’ safety behaviour.

Our discussion of the risk perceptions associated with drugs has so far reflected only one aspect of perception, namely the aggregate response of the public as individuals. Many of the problems with risk perception that drug regulators face, however, stem from two other processes of forming what appear to be public perceptions: (1) the actions of “victims”, lawyers and judges, and (2) the actions of interest groups with hidden agendas as discussed below.

The fact that prescription drugs are used by persons at higher risk

81 Id. at 110.
than the population at large means that fatalities are likely to be spuriously correlated with their use. The uncertainties inherent in the practice of medicine, coupled with the natural uncertainty of product innovation, create ambiguities with respect to the management of medication for particular patients. Regulators may view a drug as beneficial from the statistical point of view that must guide their decisions in the public interest. In specific cases this drug may be viewed by the court (justly or unjustly) to be responsible for adverse effects incurred by a specific patient (e.g., someone who is oversensitive to the toxicity of the drug).

Litigation tends to create a focal point for the formation of small, but highly emotional groups, with heightened risk perceptions. This process creates "news" that allows narrowly based risk perceptions to disproportionately influence public risk perceptions. This in turn influences the political process. The strong concentration and dedication of people with amplified risk perceptions regarding drug safety (e.g., victims of adverse reactions) and the diffuse distribution of people who enjoy the drug benefits create an imbalanced political perspective. The outrage of identifiable victims, rather than the invisible, statistical net benefits of regulatory action, will dominate public opinion. This phenomenon requires a communication strategy designed to inoculate public opinion regarding benefits before a crisis emerges because later communications may be regarded as "white wash."

The second process to be managed is the social amplification of risk perceptions by groups with hidden agendas. Those adversely affected by drugs provide such groups an opportunity for public expression of frustration and resentment. Crisis management is required, but, again, a long term communication strategy will reduce the chance that adverse reactions will be viewed as evidence of indifference to safety.

Such a communication strategy may aim to fulfill several objectives. First, it may try to reduce public fears that can paralyze the regulators...
and the market — and pose increased risk. Integrity and openness creates an atmosphere of trust that alleviates public fears. It also depoliticizes the risk issues in the long run.

Second, it may seek to mitigate crises of confidence in regulatory agencies and to anticipate feelings of outrage that may result from low probability events by improving the dissemination of scientific information to the public. However, scientists are not necessarily the best risk communicators. The development of communication support systems (e.g., teams consisting of both scientists and communications specialists) to provide information to the public is part of what we earlier called a long term inoculation strategy. Moreover, crises of confidence can be avoided with post-market surveillance to provide early warnings of adverse drug reactions.

Finally, it may try to encourage behaviour of physicians and patients designed to reduce safety risks with strategies such as the “brutal candor” use screening system. This system requires the patient to learn about a drug and to be tested before being permitted to use it. Also, e.g., provincial benefit approval systems may require doctors to use only certain drugs if they expect their costs to be reimbursed by the plan. Further, behavioural modification strategies commonly used in marketing may be used. However, these must be carefully targeted and well designed to be effective, and ethical concerns must be carefully considered. Strategies to improve “mental models” associated with drug use (i.e., to correct misperceptions about facts) and encourage informed behaviour are perhaps less effective in the short run but more acceptable in a democratic society in the longer term.

To be effective, a communication strategy must be integrated and it must consider synergies and externalities. Piecemeal approaches may

82 MacGregor, supra note 7.
83 Supra note 1.
create contradictory impacts and undesirable (or unanticipated) effects.

Summary and Conclusions

We have discussed how public risk perceptions interact with the regulatory process used to promote public safety. We have given special attention to the many reasons why regulators must understand how public risk perceptions are created and influenced. We have shown how perceptions play a key role in the identification of risks, their estimation and evaluation, and strategies for their reduction and control. We have applied this conceptual framework to the important area of public risk perceptions in drug safety evaluation and conclude that a strategic approach to communications can reduce counter productive impacts of public perceptions. Such an approach can also provide a welfare-improving reflection of public risk preferences; consistent with the prime objective of informed individual and public decisions.