SAFETY, RISK AND REGULATION

Basic Concepts for "Safety" Risk Analysis

by **Ludwig Benner, Jr.**

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ABSTRACT

THIS PAPER discusses the applicability of risk-based concepts to "safety" problems generally. "Safety" programs exist to fulfill future expectations of people to live out their useful days free of accidental interruption. Utilizing a proposed generalized accident theory, the author describes the probabilistic nature of the existence of the ingredients necessary for an accident to occur, and the effects of man's capability to change such probabilities. An "accident risk" approach to "safety," in terms of the probable accidental reduction in useful life span associated with an activity, is presented. Establishment of an acceptable accident risk level as a "safety" objective, and the effects of risk creation and risk bearing on the establishment of that objective are discussed. "Safety" regulation is described as a risk-setting function, and the implications of that view in terms of "safety" responsibility, authority, and accountability are explained. Effects of a risk-based approach on safety data generation and collection are suggested. Additional research needed to permit implementation of the proposed approach is described.

FORWARD

In the late 1960's, Chauncey Starr[13†] presented some pioneering analyses of accidents and patterns of fatalities in the public use of technology, as documented observable results of the cumulative operations of our social system, to try to achieve a better understanding of the general problem of balancing utility versus total societal costs in our society. Among the measures used in his studies has been "risk" of fatal or injury producing accidents. His work suggests the acceptability of certain levels of risk associated with various types of activity. He suggests that a risk trade-off range is available for social policy determination.

In January, 1971 the National Transportation Safety Board adopted a Special Study "Risk Concepts in Dangerous Goods Transportation Regulations."[3] That study described the development of safety regulations for dangerous goods transportation, and the difficulties attributable to the absence of a unifying conceptual basis of any kind during their development. A conceptual framework for development of safety regulations was presented, based on quantifiable risk. The concept was considered to have application to the broader field of freight transportation safety.

**Department of Transportation*

NOTE: *The views expressed in this paper are those of the author and do not necessarily reflect the positions of the National Transportation Safety Board.*

†*References cited in this article may be found at the conclusion of this article.*

Questions stimulated by these studies, and subsequent exchanges of views flowing therefrom, have suggested the opportunity to enlarge the risk-based approach to "safety" problems generally. This paper examines dilemmas in "safety" concerns and, utilizing a proposed generalized accident theory, presents an accident risk approach to "safety" in terms of the probable accidental reduction in useful life span. Establishment of an acceptable accident risk level as a "safety" objective and the effects of risk creation and risk bearing on the determination of that objective are discussed. It is hoped that application of the risk-based approach to "safety" concerns will, in time, permit a more rational grasp and resolution of the many safety issues affecting private and public policy, investment and regulatory decisions in our society.

The author wishes to acknowledge, with particular gratitude, the work of Dean Chauncey Starr, which has inspired confidence in the ultimate success of a risk-based approach, and the numerous contributions and encouragement in the development of an understanding of accident mechanisms provided by my colleague at the Safety Board, R. Emerson Harris.

"DOUBLE STANDARDS" FOR SAFETY

A curious public and private ambivalence toward "safety" in our society is receiving increasing attention of late. We seem to have numerous "double standards" in our concerns for "safety" and our responses to these concerns. For example, we find an increasing concern for "safety" which is delaying erection of new nuclear-powered electrical generating plants, yet we tacitly accept procrastination in applying correspondingly high safety standards to the activities in our homes, where today the number of injuries is thousands of times greater. The refusal of most new car buyers to invest in injury-reducing seat belts in automobiles, when these accessories were optional, is well documented, yet despite expression of the public view toward its own "safety" our government established a mandatory requirement for automobile seat belts. Casualties from flooding of homes built on flood plain lands could be eliminated by prohibiting their occupancy or construction, yet where is this being done? As parents, we are willing to spend all the resources at our disposal for treatment of threatening childhood illnesses, yet we freely encourage the same children to play with bicycles, wagons and similar vehicles capable of producing fatal injury during their use, with almost no instruction or training for avoiding such injury. Employees insist on hard hats and safety shoes in the work place, yet their non-work activities are largely devoid of discretionary safety paraphernalia. Examples of such double standards toward "safety" exist all around us. There is a sometime concern about "unsafe" circumstances and accidents associated with certain activities, yet our personal and public efforts and commitments can best be described as erratic, or perhaps inconsistent. In transportation, our apparent ambivalence toward drinking and driving is clear to everyone involved with "safety" work.

Why does this ambivalence exist? Is there some explanation which might help us to understand this dilemma, and rationalize our responses? What "safety" concerns should we be trying to meet? How can they be met? Who should be meeting them? What is the proper role for all the parties involved? What is the rationale for each role?

Informative answers to these vexing questions about "safety" would be helpful for reconciling the diverse views and opinions which underlie this ambivalence about accident concerns and responses. Is there some explanation which can link these concerns and responses to permit their reconciliation in the future? The objective of this paper is to stimulate the development of the understanding needed to achieve this reconciliation.

CONCERN FOR "SAFETY"

Let us first examine this concern about accidents. In our society life is a precious, unique and intensely personal state. A powerful urge to prolong life as long as possible, without disability, motivates individual concern about accidents. The individual is not so concerned about a statistical death, as he is about his own,[5] but the concern is only a matter of degree regardless of whose death or disability is being contemplated. Accidents threaten the natural duration of our useful existence; therefore accidents are objectionable to each of us, and we seek to avoid the loss of time they might entail were we to be involved.

Other activities which threaten the duration of our existence also command our attention, such as satisfying our need for food and shelter. Therefore, the threat of accidental harm is but one concern, and occasionally we must make difficult decisions to tolerate one threat to avoid being overtaken by another. Let it suffice to say that injury-producing accidents are objectionable and in our society we desire to avoid them. It is such accidents on which we will focus in this paper, although other forms of accidental harm might receive like consideration.

This concern about the threat to the duration of our continued useful existence from accidents provides a starting point for linking the difficulties cited above. Much of the concern arises from uncertainty. This uncertainty arises in connection with our present level of understanding of what an accident is, when it can strike, what its effects will be, and what can be done to avoid it. If this uncertainty is to be dispelled, a better understanding of accidents is needed.

What is an accident? Numerous definitions of "accident" imply various concepts,[2,8] but no documented comprehensive theory has been advanced or accepted which would lend itself to analytical treatment of the concern described above. There exists no theory to describe what an accident is; how, when and where it begins and ends; the factors an accident encompasses; and how and why it occurs. In the absence of such a theory, it is little wonder that confusion and consternation about "safety" are so prevalent. Without an understanding of accidents, how can the concern about "safety" be rationally translated into a rational response by all the diverse parties involved or affected?

A GENERALIZED ACCIDENT THEORY

General agreement exists that an accident is an occurrence in a sequence of events. It is also generally agreed that an accident involves injury (although not always human injury), that it is not planned or intended, and that it can strike at any time.[2] Beyond this, agreement lessens.

The author has found it very helpful to incorporate other considerations to achieve a workable understanding of accidents. An accident occurs in connection with an activity involving certain interrelated elements. These activities are conducted in the presence of conditions of vulnerability (interrelated with each other or the activity) which conditions must exist for an accident to be possible. An accident begins when one of the elements engaged in the activity is overtaxed beyond its ability to recover from the overload, and can not resume functioning within the limits of its capability again in the continuity of activity. The events constituting the accident mechanism then progress or cascade due to the successive overtaxing of other interrelated constituents of the activity (causing injury or failure); they continue to progress until the overtaxed constituent elements cease to impose loadings in excess of the next contiguous element to recover without functional disability.

This progression is crudely analogous to toppling an array of dominoes, in which the first domino topples the next until the placement or configuration of the next domino is such that it withstands the force of the preceding domino without falling. There the chain of events ends. In each instance, the condition of the successive domino must be within certain limits for it to be toppled or to remain standing.

A graphic representation of these considerations is shown in Figure 1.

An accident begins when the activity, conditions of vulnerability, and interrelationships present combine to overtax the capabilities of one (or some-

AN OUTLINE OF A GENERALIZED ACCIDENT THEORY

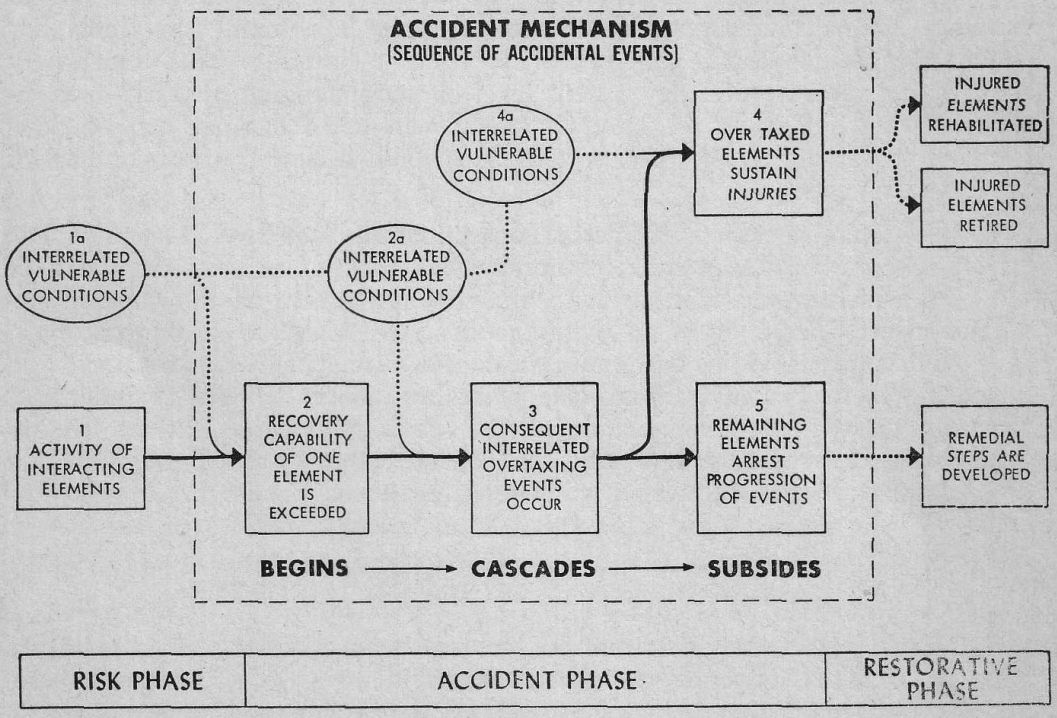

FIGURE 1

times several) of the constituent elements present, beyond the ability of that element to recover and resume its function within the activity.

An accident mechanism progresses when the initial overtaxed element imposes overloads on successive elements of the activity, in the presence of necessary conditions of vulnerability, and cascades sequentially along either a single path or along several branch paths in the same manner.

An accident subsides and comes to an end when contiguous elements of the activity are impinged by the cascading events, but are not overtaxed beyond their capability to absorb the loadings and continue to function within their expected limits.

It is significant to note that the activity involved may be normal or abnormal; that the conditions of vulnerability associated with the activity may be normal or abnormal; and that the interrelationships may be normal or abnormal. Transcending of the recoverable capability of the first overtaxed element may occur during normal activity, through error, failure, "act of God" or otherwise. Circumstances which must have been present for this to occur can usually be identified in the analysis of an accident—either real or postulated.

Cascading events in the accident mechanism progress according to natural laws; these events can often be reconstructed logically after an accident.

The same considerations apply to "near misses" which can be considered aborted accidents. The difference lies in the interruption of the progression of events which would constitute the accident mechanism before injury occurs. Thus, these unwanted events must have associated with them some injury before they qualify as accidents.

After an accident mechanism has occurred, restoration takes place. When injury has been fatal, rehabilitation is not applicable, but the restoration process still occurs. Without going into detail, it is possible to consider the post-accident "safety measures" as part of the restoration process for the society, and therefore it is depicted on Figure 1 in this phase.

Based on this theory of an accident, a rational approach to "safety" in response to the concern previously described may be feasible.

A RISK APPROACH TO "SAFETY"

For an accident to occur in connection with an activity, all the necessary elements, conditions of vulnerability and interrelationships must be present. If any one of the necessary ingredients is absent, or if it is present in the activity but not in the necessary relationship, that accident mechanism can not occur. Assuming all the ingredients are present in the necessary relationship, every time the activity is undertaken an accident will occur.

In the real world, consisting of complex activities and even more complex people engaging in activities, the likelihood of the necessary ingredients being present during a specific activity is usually quite low, as evidenced by the relative infrequency of accidents. If the necessary ingredients are not always present, but can be, there must exist some finite probability of their

presence, in the necessary relationships, during an activity. Therefore, the occurrence of the accident mechanism or injuries produced in the accident can be viewed in terms of the probable existence of the necessary ingredients and relationships which must be present for the accident mechanism to begin and progress to a conclusion. This suggests further that if one or more of these "must" elements, conditions or relationships can be identified and removed or controlled properly, the possibility of the accident can be diminished. It follows that an understanding of the accident mechanism and the necessary ingredients is essential if "safety" measures are to be effective, and the possibilities of future accidents are to be successfully reduced.

The likelihood that an accident will occur, and the likely extent of the injury if it does occur, constitute the accident-related *risk* (or "safety" risk) associated with the activity under way prior to an accident. This concept can be expressed:

$$\text{ACCIDENT RISK} = \frac{\text{probable accidental reduction in expected useful life span}}{\text{unit of activity being undertaken}}$$

"Probable" takes into account the probability associated with the occurrence of an accident as well as the injury. "Accidental reduction" encompasses fatal as well as permanently or temporarily disabling injury. "Useful life span" is applicable, in terms of time, to human or non-human entities. Unit of activity is the time that entity is engaged in the activity with which ingredients of an accident may be associated. During the conduct of a continuing group or class of activities, the average of these risks can be considered the level of risk for these activities. When our concern for "safety" is with a group or class of activities, the risk level can provide a common measure which links our concern to other activities for comparative purposes. When our concern is for the "safety" of a specific activity, risk can provide the same commonality for comparison. Here, then, is a common measure of the "safety" ingredient for evaluating an activity.

The probabilities associated with the existence of each element, condition or relationship may vary naturally, or—very importantly—*they can be made to vary by human intervention*. Modification of any one of the elements or relationships for a potential accident mechanism can change the risk level or the risk for that activity. For example, by installing lightning rods, man can reduce the risk of accidental injury associated with a naturally varying element affecting his activities. By driving only when sober, a motorist can reduce the risk of accidental injury associated with elements introduced by man. Because of the vagaries of both nature and man, the condition or actions of either cannot yet be predicted with certainty. This means that they can be predicted probabilistically at best. Despite this weakness, continuing research to identify the determinant variables affecting both suggest that this weakness should not prove fatal to the approach proposed in this paper.

The capability to change accident-related risks constitutes the source of many difficulties in treating "safety" in our society, yet at the same time it provides an opportunity to undertake a rational approach to the concern about accidental interference with our lifespan. Some of the difficulties occur when we consider who should be permitted to change accident-related risks, and

what activities should be considered. What changes should be accepted, under what conditions, and by whom? What risks are satisfactory and what risks should be rejected? What is the role of risk in the decision-making process?

ACCIDENT-RELATED RISK TAKING

Confining "safety" to consideration of accident-related risks is useful because it clarifies the role of safety in decision-making. In this sense, "safety" will usually be found to be but one factor in the decision to engage in an activity. It may be the determinant factor in deciding *how* to carry on the activity, but it is less frequently the determinant consideration in deciding *whether* to undertake the activity. Other factors can—and frequently do—outweigh safety in arriving at the "whether" decision. Often the trade-offs weighed in arriving at a decision to undertake an activity are difficult to evaluate, particularly when we are constrained by economists' view of values. In view of the apparent prevailing concern for the interruption of lives in accidents associated with any activity, the effort to quantify the "value of lives saved" as the yardstick for measuring "safety" appears misguided, even for resource allocation purposes. When risk is viewed as the probable accidental time lost or reduction in life span per unit of activity (exposure), risk can provide a useful safety measurement for weighing comparatively the desirability of undertaking an activity or of funding a change for "safety" purposes. Development of risk as a "safety" yardstick has been initiated; Starr,[6] for example, has described different levels of risk which exist for various activities in related terms.

The concept of using probable reduction in life span resulting from accidents during an activity as a measurement of risk for "safety" purposes might be successfully related to other factors with which "safety" is competing for attention and resources. For example, it has been alleged that the 20% of the U.S. population with the lowest family incomes have an infant mortality rate that is four times what it should be, and a life expectancy that is reduced by more than 16 years.[7] How many activities are so "unsafe" as to result in an equivalent reduction in the life span of the parties affected by the activity? How much of the 16 year reduction in life span is attributable to "unsafety"? Perhaps such comparisons might provide more meaningful insights for determining priorities for allocation of national resources than the economics of "lives saved."

This is not to suggest that economic considerations have no role in risk-based approaches to "safety." Focusing on risk does not rule out economic comparisons. If it is determined that a risk is too high, and that it should be reduced to an acceptable value of say "x," the alternative actions or changes by which this could be accomplished can be compared for their incremental effect on *both risk and cost*. The benefit is attainment of the desired risk level, rather than "lives saved." Thus the "value of a life" for safety purposes becomes moot; there remains only the need for a determination of risk and cost of changing the risk.

The foregoing describes an approach for determining the comparative efficiency of alternative safety actions in achieving a desired level of risk.

It does not deal with the determination of what risk level is acceptable or unacceptable. The selection of the desired risk level to be achieved, and the selection of the most desirable action to achieve that level are separate and discrete decisions. The former corresponds to the "level of safety" which will be acceptable to the parties affected by the activity, and the latter relates to the "safeguards" to be employed when the activity is undertaken.

"Safety" programs exist to fulfill future expectations of people to be free from accidental interruptions in their useful lives. Accidents are events which imply surprises, in that they are deviations from the desired and expected accident-free future existence of the people affected. Viewing "safety" probabilistically, in terms of risk, addresses the objective of safety concerns of these people, or their concern for longevity without accidental interference. Therefore, accident risk concepts dealing with the future life expectancy of individuals are responsive to the public's concern for "safety," whereas the "value of lives saved" approach, addressing the efficiency of safety programs rather than their objective, misses the mark.

The determination of the objective of safety programs, i.e., the level of risk which is acceptable or unacceptable, involves a complex decision making process about which little is known today. The emergence of a consensus for the "target" level of risk which safety programs should strive to achieve incorporates many trade-offs (many involving non-safety considerations) which are not well understood. Herein lies an additional facet of the dilemma between concern for safety and safety actions. Specifically, differences in viewpoints about what constitutes an "acceptable" level of risk arise among persons having differing exposure to the accident risks being considered.

RISK TAKING AND RISK BEARING

A further link to understanding our ambivalence toward "safety" can be derived from examination of the relationship between the decision which establishes the risk of accidental injury and the bearing of the risk resulting from that decision.

The decision which *establishes* a new accident-related risk or risk level may take the form of:

- introducing a change,
- authorizing a change,
- preventing a change, or
- setting criteria for change.

Introducing a change in the activity, conditions or relationships which affect the accident-related risk may occur when a new activity is introduced, or when a change is made within an existing activity. In either event, the new risk needs to be determined before the decision to proceed with the new activity or change can be responsibly evaluated.

Authorization to proceed with a change constitutes another form of the risk taking decision. This consenting authorization can be granted by a variety of parties, including individuals who introduce the risk, individuals who will be placed at risk, governmental agencies, legislators, and others. While the

inclination is to consider only governmental regulators, other parties' roles must not be overlooked, particularly where authority to regulate does not now exist. The authorization to proceed may be explicit or implicit, by specific direction or by neglect, by careful analysis or by instinct, by logical conclusion or by "expert judgment."

Prevention of change establishes new risk when the circumstances in which an activity is being conducted change in a manner that places the existing activity in greater jeopardy. By repressing needed improvements, risks from doing "the same old thing the same old way" may increase without detection.

Setting standards or criteria for new activities or change, without analysis of the effects on risk, can also establish new risks without detection. Quality standards for standards-setting processes that address activities with which accidental injury may be related, when absent, increase the likelihood of increased accident risk.

In complex activities, the accident risk associated with that activity can be influenced by any of the variety of sources which introduce or exercise control over any one of the elements, conditions of inter-relationships. Analysis to identify the true decision-maker who introduces controls, either for the activity or for one of its constituents, is a necessary function in risk analysis, as will be seen below.

The *bearing* of the risks which result from the above actions takes on special significance in these circumstances. As the establishment of risk of accidental injury is often diffused or unclear, so is the bearing of the risk created. Risks may be borne by the party introducing the risk as occurs when a chemist prepares a small batch of a new chemical in his laboratory or when consenting adults experiment with lethal hallucinogens. They may be borne unwittingly when they are undetectable by the risk bearer. The risk bearer may bear a risk because it is mandatory or necessary for him to do so. He may bear a risk because in his discretion he elects to do so. But, unless he introduces and controls the risk, he rarely has the option of refusing to bear the risk. Unwillingness to bear some risks, however, is at the root of much of today's controversy, as illustrated by the concern over the increasing number of nuclear-fueled power generating plants, and the unknown risks which may accompany them.[7,12]

The relationships between risk creator and risk bearer appear to lie at the heart of the apparent ambivalence about "safety." Risks can be created by several classes of persons, such as individuals acting unilaterally, participants in a joint activity, governmental institutions, and even bystanders. Any of these entities can introduce the change or changes which result in the setting of a new risk.

Risks can be borne by individuals engaged in an activity, or participants in or bystanders to an activity, irrespective of who created the risks. By displaying the relationships which can be involved, the need to consider who should set the risk level becomes evident. In Figure 2, several relationships are shown.

BASIC RISK SETTING RELATIONSHIPS

S = Self or Individual **B = Bystanders Exposed to Activity**

P = Participant in Activity **G = Governmental Institution**

Change Introduced By	Risk Borne By	Risk Level Should Be Set By
S	S	S
S	S&P	S&P
S	B	G
P	B	G
B	B&P	G
G	B&P	?

FIGURE 2

For "safety" purposes, it seems rational to assign the authority, responsibility and accountability for self-imposed accidental risk taking to the risk taker alone, as shown on the first line on Figure 2. It seems equally rational to conclude that when two parties consent to the joint undertaking of an activity which can bring each or either of them accidental harm, they should be free to do so (if in fact no one else is placed at risk by their acts.) However, when bystanders become involved, the "freedom" to take risks should logically be inhibited.

Application of these principles to "safety" issues in our complex society is not always obvious. For example, when an individual assumes a self-imposed risk, and subsequently suffers injury in an accident which has occurred because of his unilateral decision, is the principle still valid if the restorative burden is imposed on other elements of our society, such as family, employer, etc. Where two parties to a negotiated bilateral "agreement" to introduce and bear risks have unequal bargaining power, as might exist between a large employer and an employee, does the "joint undertaking" principle still apply? Where risk to bystanders is so low that no serious injury is likely, should introduction of that risk be inhibited for "safety" reasons? How should risks introduced by government, which represents the "public," be accommodated?

Consideration of these questions in terms of risk-setting decisions permits further clarification. Risk setting is the establishment of the level of risk which will be acceptable to those affected by the activity. The mechanism for setting these risk levels should consider and accommodate the needs (or perceived needs) of all parties and their risk of accidental injury, in some rational manner, if all parties are to find the decision acceptable. This suggests that where dissatisfaction or uncertainty exists with the "safety" of an activity involving two or more parties, there is a problem with either the risk level or the risk-setting mechanism. For example, an entrepreneurial entity wishing to introduce a new consumer product, carrying with it some risk of acci-

dental injury, would probably be inclined to accept a higher level of risk than the user who might elect to purchase it, particularly if the risks were known with equal clarity to both parties. In transportation safety, the absence of a mechanism for emergency response personnel to effectively participate in the risk-setting mechanism in the transportation of hazardous materials causes dissatisfaction with the "safety" in transportation of these materials. Therefore, further refinement of Figure 2 is indicated. Identification of the nature of the risk bearing for each entity involved in an activity, the responsibility for identification and disclosure of the risks, the decision mode for establishing limitations to control the risks, etc., shed further light on the relationships between risk creation, risk bearing, and risk setting. See Figure 3. Clearly, some relationships require further study. Where government, for example, can create the risks which will be borne involuntarily by bystanders, as can occur through regulatory inaction in the transportation of hazardous materials by for-hire carriers, who should be responsible for risk disclosure and the setting of the risk level? Nevertheless, this approach seems valid, and ought to be expanded to address all the functions of government, to ascertain the applicability of each function in risk setting for the various risk creating/risk bearing relationships affecting "safety."

Further consideration of the matrix in Figure 3 suggests additional thoughts of interest. For example, what is the proper role of the consumer advocate—either public as contemplated in the Consumer Safety Act,[9] or private as practiced by "Nader"-type organizations? How do these roles relate to the risk creator or bearer in terms of their responsibility, authority or accountability in the establishment of risk levels involving possible accidental injury? How can the unwilling risk taker express his unwillingness and get a rational response in the face of these relationships? What is the role of government, if any, in risks created and borne by bystanders, or those established by government itself?

Safety Regulation as a Risk-Setting Decision

A governmental safety regulation has been described as a governmental solution to a problem.[1] The not uncommon implementation of new safety regulations in reaction to accidents might lead to this interpretation. However, in view of the accident theory and risk considerations described above, a governmental safety regulation can be seen to be, in fact, a risk-setting decision, implemented by the establishment of some control over the activity, the conditions of vulnerability or the relationships posing risk of accidental harm to certain classes of risk bearers. The need for intervention by government in various risk-setting decisions can be logically considered according to the principles described above when the relationships between risk bearing and risk creation become visible, as in Figure 3.

For example, the role of government in wholly private risks established unilaterally (if such risk do in fact exist) should be nil. Its role in wholly private risks established bilaterally is less obvious. Governmental participation might logically be limited to the disclosure and restorative processes if equal bargaining power exists; if this power is unequal, intervention as a mediator in resolving differences in risk levels acceptable to the parties might be persuasively argued. The imposition by government of the risk level to be borne

EXPANDED RISK SETTING RELATIONSHIPS

S = Self or Individual
P = Participant in Activity
B = Bystanders Exposed to Activity
G = Governmental Institution

Change Introduced By	Risk Borne By: Voluntarily	Risk Borne By: Involuntarily	Disclosure Of Risk By	Risk Level Set By	Decision Mode*
S	S		----	S	U_s
S	P		S	S	U_p
S		B	S	G	U_b
S	S	P	S	S&P	B_n
S&P	S&P		S, P	S&P	B_c
P	P	B	P	P&G	B_b
B	B		?	B	U_s
G		PB	G	G	U_b
G	P	B	GP?	GPB?	M?

*U_s = Unilaterally on own behalf
U_p = Unilaterally for all participants
U_b = Unilaterally for all bearers
B_n = Bilaterally by negotiation
B_c = Bilaterally under standards
B_b = Bilaterally with G for bystanders
M = Multilaterally by all Involved

FIGURE 3

by equal private parties seems an improper use of governmental power; the establishment of a mechanism for resolution of differences by such parties seems more rational.

Elaboration of the principles previously discussed in relation to a specific safety problem area is helpful. For example, consumer product safety legislation is currently topical. The stated purpose of the Consumer Safety Agency created by the Consumer Safety Act[9] in S3419 is ". . . to promote the public health and safety by protecting consumers against injury resulting from the use of foods, drugs or consumer products." The legislation concerns risks, which are introduced by manufacturers, producers and others who unilaterally put consumer products into the stream of commerce, and which are borne by consumers or bystanders as a result of decisions to acquire the product. Analysis of the functions incorporated in this legislation indicates that S3419 considers at least the following risk-related functions:

- introduction of risk elements
- identification of risk elements
- disclosure of risk elements or risks
- evaluation of risk elements or risk levels
- acceptance of risk levels
- bearing of the risk of injury
- control of risk levels.

For a manufactured consumer product, the parties concerned with risk of injury associated with the product include the manufacturer, purchaser, bystanders and the government. The assignment of the responsibility, authority and accountability for the above risk-related functions contemplated under S3419 is summarized in Figure 4. Analysis of this matrix suggests difficulties with the approach which can be discerned by application of the risk principles set forth earlier. For example, the act holds the manufacturer exclusively responsible for the introduction of the risk elements associated with the product. However, the introduction of risk elements can occur with the manufacturer during manufacture or with the user, during the use activity which is under the purchaser's control. Thus, responsibility for the controlling ingredients necessary for an accident probably should not be assigned to only one of the two parties who determine the risk of injury if the total risk is, in fact, to be controlled successfully.

Note also that the bystander, under the act, is not considered to be responsible or accountable for any of the functions. In practice, bystanders can and occasionally do bear the risks arising from accident ingredients introduced by either the manufacturer, or the purchaser, or themselves; yet the manufacturer is held solely accountable for control of the risk. Even though the purchaser can introduce risk elements, the act does not consider him responsible or accountable for disclosure of the additional increase in the risk level which he may contribute.

The purchaser may elect to purchase or not to purchase a given product, yet the manufacturer and the government share the risk acceptance decision under S3419. Similarly, the manufacturer and the government share the responsibility and the authority for the control of the risk levels once they are

Example of Responsibility, Authority and Accountability of Parties concerned with risk of injury associated with a Manufactured Consumer Product, as contemplated by S-3419[9]

E = Exclusive S = Shared N = None c = Controlled by S-3419 nc = Not so controlled

Function		Manufacturer (M)			Purchaser (P)			Bystander (B)			Government (G)		
		Res	Auth	Acc	Res	Auth	Acc	Res	Auth	Acc	Res	Auth	Acc
		1	2	3	4	5	6	7	8	9	10	11	12
Introduce Risk Element	1	E_c	$S_c(G)$	E_{nc}	N	N	N	N	N	N	N	$S_c(M)$	N
Indentify Risk Elements	2	$S_c(G)$	$S_c(G)$	$S_c(G)$	N	N	N	N	N	N	$S_c(M)$	$S_c(M)$	$S_c(M)$
Disclose Risk Elements	3	$S_c(G)$	$S_c(G)$	$S_c(G)$	N	N	N	N	N	N	$S_c(M)$	$S_c(M)$	$S_c(M)$
Evaluate Risk Elements	4	$S_c(G)$	$S_c(G)$	$S_c(G)$	N	N	N	N	N	N	$S_c(M)$	$S_c(M)$	$S_c(M)$
Accept Risk Level	5	$S_c(G)$	$S_c(G)$	$S_c(G)$	N	N	N	N	N	N	$S_c(M)$	$S_c(M)$	$S_c(M)$
Bear Risk of Injury	6	N	N	N	$S_{nc}(B)$	E_{nc}	N	$S_{nc}(P)$	N	N	N	N	N
Control Risk	7	$S_c(G)$	$S_c(G)$	E_c	N	N	N	N	N	N	$S_c(M)$	$S_c(M)$	N

E_c = Manufacturer held Exclusively accountable under S-3419
$S_c(G)$ = Authority divided between Manufacturer and Government
E_{nc} = Manufacturer held exclusively accountable, by means other than S-3419
N = No role contemplated
$S_c(M)$ = Authority divided between Government and Manufacturer
$S_{nc}(B)$ = Responsibility divided between Purchaser and Bystander
$S_{nc}(P)$ = Responsibility divided between Bystander and Purchaser

FIGURE 4

established, even though a third party may contribute to the risk level outside the scope of the control established by these two parties. Thus, the act seems to incorporate an approach which may be destined to be unsuccessful in achieving its declared objective.

This is not to suggest that the effort is without merit. For example, even though the seller/buyer relationships indicate a "joint risk undertaking," the unequal ability of the parties to identify the risk involved with the manufacture and use of a product suggests that a disclosure role for the government might be appropriate. Safety standards may be set only for accident ingredients introduced by one of the parties, but such unilateral action may serve to reduce the risk level dramatically if the contribution of the product to the probability or severity of accidental injury is predominant. This relationship remains to be identified analytically for most products to be regulated.

If the establishment of governmental "safety" regulations is viewed as a risk-setting function, the post-facto surveillance of the effects of the regulation could be enhanced by simply measuring the injuries and the exposure involved with the regulated activity. Alternatively, pre-accident confirmation of the achievement of the desired risk level might be attainable by measuring the frequency of the occurrence of the individual conditions of vulnerability or relationships, which are being addressed by the "safety" regulation, either on a routine or a sampling basis. The impact of this change in the philosophical approach to the data gathering activities of the government could be expected to be of great magnitude. Present impediments to gathering of "safety" data, resulting from constraints imposed to meet civil "due process" requirements, might be successfully overcome with this new approach.

If a safety regulation is a risk-setting decision, it is imperative to note that only those safety regulations which have a perceptible impact on the risk are necessary. Where the imposition of a safety regulation on an activity does not produce a significant reduction in the risk, it is of no value, and in fact, may be detrimental in that it dilutes the effort to limit risk. To be successful, then, a safety regulation must address those elements of an accident mechanism which, if uncontrolled, would increase the risk level beyond acceptable limits; those elements which, if present, would not result in unacceptable risks can be left unchanged.

Research Requirements

If this approach to "safety" as a decision factor in determining whether and how to undertake an activity is valid, research is necessary in several areas. First, the public's understanding of what constitutes an "acceptable" level of risk for different types of activities, and for different relationships between the risk creator and the risk bearer, need to be studied, probably from a "market research" viewpoint. While Starr's work[6] has disclosed current risk levels for numerous activities, and is a most valuable contribution to the generalized risk approach to "safety," it does not shed sufficient light on what level is acceptable. For example, if the "disease level" were acceptable, why would efforts to reduce the death toll from cancer be receiving such urgent national attention?

Secondly, a methodology for estimating risk or risk levels needs to be established. These needs have been discussed by the National Transportation Safety Board[3] and others. Efforts to develop such a methodology are being initiated in the transportation field[10,11] and for consumer products.[4,9] The scope of the ultimate effort appears to be large; properly organized, the burden of this effort on any one party should not be excessive. Undoubtedly, the benefits which would be derived by a broad cross-section of our economy, if such methodology were available, will stimulate the research needed to produce a satisfactory methodology for this purpose.

A third area of inquiry should address the relationship between the risk creator, the risk bearer, and the risk setter in those decision processes now involving governmental roles, and in those processes for which a governmental role is being contemplated. The principles proposed in this paper for determining the relative roles for each of the parties need to be tested against current practices, and the changes which their application might introduce need to be assessed.

Finally, if the outline of the generalized accident theory proposed herein is not acceptable, it is imperative that research leading to the development and adoption of an acceptable theory be initiated without delay. The role of "safety" in our decision-making processes will continue to be obfuscated until an acceptable theory can be adopted and utilized in all future "safety" efforts.

As the methodology for determination of risk levels develops, additional research into the collection of statistical "safety" data will undoubtedly be required. Clearly, the tallying of accidental casualties for these many, many years has not produced breakthroughs in the reduction of the total count. Perhaps the new methodologies and their resultant data requirements to confirm predicted risk levels, which have eluded us thus far, will accomplish the breakthroughs through the organized application of the best analytical tools available to our society.

Many difficulties lie ahead. Clearly, the quality of decisions to undertake an activity could be upgraded if the risk of accidental injury were known in the decision-making process. Perhaps equally significant, the visibility of risks associated with different alternatives for conducting or changing activities will encourage remedial action where the risks are greatest. The latter is especially pertinent to existing activities, of which there are now a great many producing injuries. If risks could be identified and reduced for these activities, quantum reductions in injuries would seem attainable. Identification of the risk-raising elements or relationships by pre-accident analysis of the potential accident mechanisms, rather than tallying accidents or "causes" after the fact, appears more rational for existing activities. It could reduce the lives jeopardized while the risks of current activities are being identified, day by day, in accidents.

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