# Risk and Regulation

## Voluntary Risk Assumption in Ethics, Law, & Regulatory Policy

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## I. The Problem

Life is rife with risk. This unassailable observation is often meant to calm our nerves, to counsel serenity, to render risk acceptable in this or that case. As if to say, with so much risk abounding, why not just relax and accept it as a natural cost of living?

We are naturally more discriminating. Especially regarding widely shared, societal risks induced by human artifice and susceptible to social regulation. Which risks are desirable? Which necessary? Which unacceptable? Which, in particular, have we some right to be protected against? And what regulatory measures do our rights enjoin, permit, or proscribe?

The acceptability of risk is a complex matter -- in part, as a function of the complexity of risk itself; in part, as a function of irreducible normative factors in the assessment of risk. Risk assessment--societal risk assessment--in the final analysis involves the weighing and balancing of competing societal interests and basic rights. I argue that current dispute about risk assessment and health and safety regulation has neglected crucial rights and conditions of choice, consent, and voluntary risk assumption.

### 1. Risk

Decision making 'under risk' is, strictly speaking, decision making where some meaningful (numerical, determinate) probabilities can be assigned to states of nature (or the possible outcomes of alternative decisions). For some decision theorists, 'risk,' as a strict term of art, means simply 'probability.' But we hardly want to say that there is some **risk** that, having entered, I will win $1,000,000 in the Pennsylvania lottery.

The missing dimension of concern here is the bad news we associate with risk: the potential injury, loss, or harm. But the probabilistic dimension of risk can be crucial: Risks concern us more when they involve a high probability of harm, less when the probability of harm is low.

Often, however, risks that concern us are **possible** harms that cannot be assigned determinate, numerical probabilities. Or potential harms whose statistical probabilities mean little to us.

For example, many people who fear flying are not assured by actuarial statistics, and many pay premiums for flight insurance at airports that are 30 times the actuarially fair value.

The fact that there is a .00016 probability that I will be hit by an oncoming car I do not see while pulling out of my driveway, a .003 chance that I will be injured if hit, and .0001 odds that I will die of the resultant injuries 'means' less to me than the brute fact that a friend of mine died as the result of a broadside collision when pulling out of my blind driveway just last

week. The proximity of the fatal accident, in time and personal association, makes the potential **harm** itself the more vivid and salient; the perceived risk looms larger in my mind than do the Department of Transportation statistics.

Suddenly the generalized, societal risks posed by driveways blinded by parked cars and large shade trees seem less acceptable. The risk imposed by legally parked cars that obstruct visibility seems unfair -- How to weigh the societal convenience enjoyed by some against the risks imposed on others? Probabilities don't provide the answer, and may not even be material.

Our subjective sense of risk, susceptible as it is to myriad influences, may not heed the objective, actuarial data. But subjective risk perceptions are material to our choices and preferences, and we do seem to value the right to make choices irrespective of their being at odds with the conventional wisdom or the actuarial odds: How we feel about the odds and potential harms is often all we need to know. This means that strict probabilities do not define all the relevant realms of risk.

For commonsense purposes we might define 'risk' as 'a chance of harm,' even though the term 'risk' may properly be applied to the element of **chance** itself, the potential **harm** in question, or the occasions or causes associated with the harm in question. Some define 'risk' as **exposure to** a chance of loss or harm. Since we like to talk about exposure to risk, and since the term has several proper applications, suffice it to recognize that risk as a practical concern contains an element of chance and an element of potential harm or loss.

The element of chance may be (a) quantifiable (i) as a determinate probability based on current actuarial data or (ii) as an estimate based on some statistical model or projection from historical data. Or the element of chance may be (b) indeterminate and uncertain or (c) subjectively perceived to be high, low, or negligible regardless of actuarial evidence.

## 2. Risk Assessment

'Risk assessment' typically emphasizes the science and art of **quantifying** the chance and magnitude of the potential harm involved in a given risk. Risk-benefit analysis attempts to calculate the probabilities and magnitude of potential harms against the benefits accruing to exposure to given risks. I take it that the point of risk assessment is, ultimately, to determine whether or not a given risk is acceptable. To this end, quantitative estimations of the probability and magnitude of a given hazard may be material but not sufficient.

Many find the risks of nuclear armament unacceptable. Many (more perhaps) do not. But the issue is neither joined nor resolvable on grounds of probabilities. And we hardly need finer-grained analysis of the magnitude of the hazards.

The risk perception literature teaches us that people's untutored evaluations of risk are often at odds with our theories of rational choice, contrary to actuarial indicators, and biased by all manner of factors in the presentation of facts about the risk in question. This is disturbingly true, for example, in informed consent transactions between patients and physicians: the same facts of risk presented in different ways can yield contrary choices of alternative treatments by the patient. People's choices must often be respected nonetheless, and this is not a decision-

theoretic paradox but an ethical and political one.

In many cases, the manner in which a risk is posed or mediated can be decisive to its acceptability: where we have nothing or little to say about whether or how we are exposed to a risk, no quantifiable calculation of risk and benefits may make it acceptable.

Our assessment of the acceptability of any risk will be a complex function of our respective assessments of (1) the element of chance, (2) the nature and magnitude of the potential harm in question, (3) the countervailing benefits of exposure to the risk in question, (4) the distribution of risks and potential benefits, and (5) the manner in which we are exposed to the risk.

The latter two factors involve issues of equity and rights that are irreducibly ethical. The second factor, which effectively involves the selection of certain hazards as high priority concerns, also involves the weighing and balancing of societal priorities and basic rights.

The risk analysis literature tends to be preoccupied with the quantifiable dimensions of risk assessment, the scientifically more tractable dimensions: risk measurement, economic and utility-theoretic frameworks for risk-benefit calculations, and the experimental study of factors influencing risk perception. This literature is rich and undeniably important for anyone interested in risk assessment, abatement, or management.

But decisions about the acceptability of risks and how exposure to risks should be regulated or mediated must often be made in the absence of conclusive scientific findings. And our scientifically untutored perceptions of risk, however at odds with actuarial data or decision-theoretic norms, often demand respect: we presumably have rights against exposure to certain risks to which we are averse, no matter what the odds for potential harm or benefit; and we presumably have rights to take certain risks, no matter what the chances of harm to ourselves.

The bottom line in the assessment of the acceptability of societal risks and the consequent deliberation of regulatory policy will often be determined not by risk-benefit calculations but by the weighing and balancing of the putative rights and non-fungible social values in question.

## 3. Regulation: Respecting Rights

### 3.1 The Priority of Rights to Choose and to Consent

Any case for or against the acceptability of societal risks and mechanisms for regulating them will hang in part on our understanding of our putative rights and associated social values.

I take it that the problem of deliberating trade-offs and setting priorities among competing social values and rights is paramount in defining the bounds of acceptable societal risk and the scope of legitimate government regulation.

The legitimacy of government regulation of our risky lives and industry is based on a presumption of public consent: the function of government regulation is to protect the public's interests, in virtue of which it merits public consent to its strictures. In protecting the public and individuals from unwanted harm or risk to their health, welfare, and property, regulatory constraints are presumed to respect the liberty and autonomy of individuals, their freedom to

choose whatever pusuits, so long as those pursuits do not interfere with the 'like liberty' and rights of others.

Thus, so-called 'free' choice and consent are respected on two levels: in the right to choose or consent to transactions in our individual lives; and in the right to have a say in the regulatory measures that presumably safeguard the conditions of free choice and consent in our individual lives.

Our right to be secured against harm is only apparently the *raison d'etre* of government regulation; security is only apparently the bottom-line incentive for even a Hobbesian social contractor. The priority right in question is the right to be secured against **unwanted** harm, harm which we do not choose to suffer or risk (or which we would not choose to suffer or risk if we could freely so choose).

Rights to security against harm or risk are derivative of the priority we place on respect for individual autonomy: that we give priority not to freedom **from harm** but rather freedom **to choose or consent** is evident from the importance we place on safeguarding our right to make harmful mistakes in deciding for ourselves what risks to assume in matters that concern only our own personal welfare.

### 3.2 Risks to Rights and Rights to Risk

The risks to health and safety that have come in for priority attention in recent years are not merely risks to health and safety *per se*, but at bottom risks to our rights of choice and consent. If health and safety alone were paramount, we need not be concerned about the mobility and transaction costs that constrain a worker's choice of workplace or occupation.

If health and safety alone were paramount, we would not simply outlaw ads for cigarettes that bias choice but would also outlaw their sale and purchase. Regulation poses risks to the very rights it seeks to secure so far as our rights to risk are disregarded. At bottom, it is respect for our rights of choice and consent that both enjoin and limit regulatory constraints.

This admittedly arguable hypothesis about the structure of our putative rights at least accomodates the apparently conflicting classical liberal principles of legitimate social control, to wit: coercive constraint is justified only to prevent harm to innocent parties; and coercive constraint of an individual for his own good is never justified except to safeguard his freedom to choose what he thinks best for himself: You may lay hands on a person to inform him that the bridge he is about to cross is in danger of collapsing from his weight, to assure that his decision to cross is informed and, so far, 'free'; but once he is apprised of the risk, you may not detain him solely for his own good. Mill's famous case is deceptively prosaic.

John Stuart Mill's proscription against paternalistic constraints on inividual liberty excepted cases where such constraints would on balance secure or enhance the individual's ability to make a free and informed choice: in matters that concern only the agent's welfare we may interfere only if the agent's choice is not free and informed. Mill proscribed selling oneself into perpetual involuntary servitude on the grounds that one could not invoke the principle of liberty in order to justify its perpetual abrogation.

The only justification for paternalistic constraint of individual autonomy is, by this account, respect for autonomy itself. The same priority at bottom motivates non-paternalistic constraints: to prevent **unwanted** harm to individuals, to prevent harm or risk that an individual would not choose to suffer if he were in a position to freely so choose.

The right at risk with and without state regulatory constraints is the same, namely: the right to freely choose or consent to the harms one will risk.

## 4. Neglect of Consent-Rights in Risk Assessment & Regulation

This provisional analysis of the rights and societal priorities that define the scope of acceptable societal risk and its regulation need not be accepted in order to see the pivotal importance of rights of choice and consent in the assessment of risk and regulatory policy. The risk analysis literature takes it as axiomatic that in deliberating which risks to regulate and which to allow we must at least distinguish voluntary from involuntary risk.

The problem is defining the conditions of 'free' choice, 'informed' consent, 'voluntary' risk assumption and showing how we can take better account of these factors in the deliberation of health and safety regulation. This problem is widely acknowledged but only cursorily treated in the risk-analytic literature, in the literature on regulatory policy and reform, in regulatory legislation, litigation and judicial review, and in the popular press.

The regulatory initiatives that gained such momentum in the previous decade (OSHA, EPA, the CPSC, etc.) are now under duress from libertarians and other opponents of 'big' government. The issue here is not whether the public should be protected from unwanted harm or risk to its interests in health and environmental quality. It is rather often cast as a dispute over the appropriate **mechanisms** for the regulation or mediation of these risks.

Two competing regulatory mechanisms are command-and-control regulation, which seeks to limit exposure to certain hazards by direct prohibitions on production, distribution, or consumption; and information-based regulation, like 'truth-in-labeling,' which seeks to secure the public against unwanted harm or risk through the provision of adequate information for informed choice and avoidance.

The issues between these alternatives are frequently joined on grounds of economic efficiency and economic freedom. The adequacy of information-based measures for ensuring the public health and safety, as against direct command-and-control, must certainly be assessed within some explicit framework of conditions governing 'free' choice, 'informed' consent, 'voluntary' risk assumption, and the associated rights.

This is all to say that one crucial factor in the assessment of risk and measures appropriate for its regulation is largely left out of account in the public, legislative, and policy-analytic arenas, namely (5) (Section 2 above): the manner in which we are exposed to risk, the means available to the person or population at risk to assess, mediate, or avoid the risk in question. (In the academic arena, philosophers are just beginning to address the implications of consent-rights theory for the assessment and management of societal risks. Work in this area has been begun but so far is unpublished, to my knowledge, at the Center for Philosophy and Public Policy at the

University of Maryland. Nicholas Rescher, a philosopher at the University of Pittsburgh, has a book in the works on risk and risk management; I do not know what role if any consent-rights theory plays in his project.)

The situation in the area of societal risk assessment and health and safety regulation is in stark contrast to other areas of risk assessment and management where free choice and consent are paramount, namely: biomedical policy and law regarding the manner in which patients or subjects are exposed to the risks of treatment and medical research. The critical philosophic literature in these areas is similarly rich.

I will hazard that in spite of the disanalogies between these two broad areas of risk confrontation and mediation, there are many parallel and analogous issues respecting the rights and conditions of free choice, informed consent, and voluntary risk assumption. The statutory provisions and judicial review of the requirements of informed consent in, for example, hospital law are often philosophically wanting. But consent-rights issues are faced forthrightly and explicitly, and there exists a large body of jurisprudential wisdom for their negotiation and adjudication.

Cognate conceptual frameworks have been long in development in other areas of jurisprudence and law, namely: tort and product-liability. These traditions antedate the development of issues of economic efficiency that preoccupy contempoarary jurisprudence in general and the risk-assessment and regulatory disputes in particular. Consequently, common law rights and notions of consent figure more prominently in their continuing evolution.

I suggest that contemporary disputes about risk assessment and health and safety regulation could benefit from critical philosophic analysis of our putative rights and notions of free choice, informed consent, and voluntary risk assumption; and that this analysis would do well to examine the treatment of these rights and concepts in analogous areas of ethics and jurisprudence.

## II. The Project

### 1. Project Scope and Products

I am plotting a long-term book project, *Risk and Regulation*, an analytic framework for negotiating philosophic issues crucial to the assessment of societal risks and the deliberation and public oversight of health and safety regulation.

My proposed summer project is to research and analyze one subset of these issues: the rights and conditions of 'free' choice, informed consent, and voluntary risk assumption that presumably help circumscribe the boundaries of acceptable societal risk and define the legitimate scope of health and safety regulation.

I intend to consider the comparative merits of paradigms of: command-and-control regulation (direct, coercive limitations on the production, distribution, or consumption of potential hazards to human health and safety); information-based regulation (like 'truth-in-labeling' measures, designed only to ensure that the public is adequately informed about potential hazards in order to freely accept or avoid these risks); and incentive-based mechanisms (like tort and liability law, tax incentives and compensatory insurance schemes) -- from an ethical and political-philosophic (rather than economic) perspective.

My research will cover the relevant philosophic and policy-analytic literatures, regulatory legislation, salient cases of judicial review of OSHA, EPA, FDA, and CPSC standards, risk- and cost-benefit frameworks, and studies of analogous issues respecting consent-rights in biomedical law and ethics. A representative sample of the relevant literatures (absent any legislative and agency documents) is appended. My selective focus on consent-rights issues and the most recent and salient work in the respective literatures should assure the feasibility of these ambitions. (See also the project background and development plan below for feasibility constraints.)

The hard products of the two-month summer project would be (1) an outline for the prospective book on risk and regulation; (2) a classified, partially annotated bibliography and bibliographic computer data base on the relevant philosophic, jurisprudential, policy-analytic, and related biomedical literatures; (3) a paper on the proposed topic, consent-rights issues in the assessment of societal risk and health and safety regulation, a prototype chapter for the prospective book; and (4) a paper on the treatment of generic consent-rights issues in biomedical ethics and law. (It's not clear whether the latter study would provide copy or merely footnote material for the proposed book.)

### 2. Project Background and Development Plan

I am in the second year of a two-year EVIST-funded interdisciplinary study of decision procedures for setting priorities for the regulation of toxic substances. We have been concerned primarily with the schemes used by EPA and the FDA to screen potentially hazardous chemicals for testing. My principal role has been to examine the screening schemes and subsequent priority-setting procedures regarding how explicitly they weigh and balance competing social values and distributive equity issues. Out of growing interest, I began this summer a survey of related literatures on regulatory law, policy, and reform; risk- and cost-benefit analysis; tort and liability

law.

While focused on agency decision procedures, the EVIST project has naturally provided impetus to examine the wider context of regulatory policy and reform. It was suggested at our first review panel meeting last spring that a comprehensive analytic treatment of the ethical and political-philosophic issues underlying regulatory policy would be timely. I already had a long-standing interest in issues of coercive social constraint, paternalism, and informed consent. And the apparent neglect of rights and consent theory in the risk analysis literature confirmed my sense of the need for a policy-oriented philosophic study, one that was conversant with but critical of the risk- and policy-analytic literature.

Until this last year my time has been almost exclusively monopolized by curriculum development and program administration. My administrative duties continue, without administrative release. Previous funded release time was provided for educational projects rather than standard research. I am anxious to redress this imbalance and dedicate concentrated effort to research in my long-standing albeit neglected fields of special interest: ethical theory and its applications in public policy.

I conceive the proposed project as a crucial step in the development of a pointedly interdisciplinary career and longer term research agenda in philosophy and public policy. Carnegie-Mellon University is a clearly appropriate and rich environment in which to advance the philosophic frontiers of public policy studies.

My work plan is to continue my on-going survey of the risk and regulation literature this year in order to organize a detailed syllabus of concentrated study for the summer. I am reviewing the philosophic literature on rights and consent theory to this end as well. The two summer months can then be devoted to a well ordered and generally well informed effort at intensive study and writing.

My familiarity with the institutional processes and decision procedures governing priorities for the testing and regulation of toxic chemicals (from the EVIST project that will conclude this year) will provide a wealth of relevant background material on at least a significant subset of societal hazards and present regulatory policies. My recently completed monograph on social contract theory should also prove relevant to the analysis of hypothetical consent models, to which we must inevitably appeal in basing policy on consent.

I am meeting in late October with Michael Baram (Director of the Technology and Law Program at Boston University's School of Law and Adjucnt Professor in our Engineering and Public Policy department) to discuss my prospective research agenda and book project. I hope to explore lines of possible future collaboration as well as plot a feasible strategy for selective study of the massive jurisprudential literature relevant to my topic.

I will also be consulting on the design of this project in December with Nicholas Rescher (a philosopher at the University of Pittsburgh, who I have learned has a book in the works on risk), Douglas McClean (who will be visiting from the Center for Philosophy and Public Policy at the University of Maryland and has written a working paper on risk management and consent), and Roger Kasperson (who will be visiting from the Center for Technology, Environment and

Development at Clark University and is prominently engaged in studies of risk assessment, perception, and management).

I have for review the results of a two-year study by our Communications Design Center on informed consent in hospital law: the study reviews the history and theories of informed consent in physician-patient relationships, surveys the statutory requirements of informed consent, and has accordingly redesigned a variety of consent forms. Evolving legal standards of informed consent in practical or clinical settings highly sensitized to the issues by litigation are one touchstone for testing our philosophic notions of the requisite conditions for informed consent. It will be convenient to have the principal investigators in this study close at hand for consultation.

### 3. Prospective Audience and Utility

While I intend to focus on the proprieties of government regulation, my analysis would be informative to private-sector initiatives to safeguard the public against undue risk from the production, distribution, or consumption of potential hazards: such rights and conditions of 'free' choice, informed consent, and voluntary risk assumption as prescribe and circumscribe government responsiblities would also serve as guidelines to private enterprise.

My aim is to analyze philosophic issues crucial to both the deliberation of regulatory policy and its critical public oversight: the results will be addressed to the educated public as well as agents and analysts of regulatory policy on human health and safety. An explicit analytic framework for addressing regulatory issues would be indispensable to informing the public consent, too often tacit and uncritical, that is crucial to the legitimate exercise of regulatory powers.

One premise of this project is that judgments of acceptable societal risk and the propriety of regulatory policies should not be left exclusively to policy 'experts,' appointed administrators, or elected officials without active public oversight to ensure public accountability. This is especially true where the issues are irreducibly philosophic or political: The public needs to own and address the issues of rights and non-fungible values that elude the technical apparatus of contemporary policy analysis.

Philosophers and students of rights and consent theory should benefit not only from the analysis, but also from its application to philosophically underdeveloped areas of regulatory policy. Besides illuminating regulatory issues, the application to hard cases of regulatory policy should test and refine our philosophic notions.

The proposed work would also serve as a pertinent philosophical primer for the many students entering professionally-oriented programs in public policy and administration.

A possible additional benefit of the proposed project would be to show that considerations of distributive equity and consent-rights could be made operationally explicit in regulatory deliberations, in ways that would render our regulatory apparatus more effective as well as ethically more perspicuous.

This possibility has already surfaced in our present study of the Interagency Testing Committee's screening scheme under the Toxic Substances Control Act (TSCA). At present only data relating

to the exposure levels and effects of potentially hazardous chemicals are used to screen candidates for testing and regulatory control. It would be plausible, if feasible, to include in this scheme predictable factors relating to the manner in which the target population stands to be exposed. Ethically sensitive screening factors of this sort could facilitate and refine selection among the myriad chemicals waiting in the queue for review.