



# Witches, Floods, and Wonder Drugs: Historical Perspectives on Risk Management

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WITCHES, FLOODS, AND WONDER DRUGS: HISTORICAL PERSPECTIVES ON RISK MANAGEMENT

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# FOREWORD

This paper was prepared for presentation at the <u>Symposium on Societal</u>

<u>Risk Assessment: How Safe is Safe Enough?</u> held in Warren, Michigan,

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Most of the research was done while the author was a member of the staff of the International Institute for Applied Systems Analysis, Laxenburg, Austria. The paper was completed at the Institute of Animal Resource Ecology, University of British Columbia, Vancouver, British Columbia, Canada.

#### ABSTRACT

Risk is a people problem, and people have been contending with it for a very long time indeed. I extract some lessons from this historical record and explore their implications for current and future practice.

Socially relevant risk is not uncertainty of outcome, or violence of event, or toxicity of substance, or anything of the sort. Rather, it is perceived inability to cope satisfactorily with the world around us. Improving our ability to cope is essentially a management problem: a problem of identifying and carrying out the actions which will change the rules of the game so that the game becomes more to our liking.

To cope better is to better understand the nature of risks and how they develop. It is naive and destructive to pretend that such understanding can carry with it the certainties and completeness of traditional science. Risk management lies in the realm of trans-science, of ill-structured problems, of messes. In analyzing risk messes, the central need is to evaluate, order, and structure inevitably incomplete and conflicting knowledge so that the management acts can be chosen with the best possible understanding of current knowledge, its limitations, and its implications. This requires an undertaking in policy analysis, rather than science.

One product of such analyses is a better conceptualization of "feasibility" in risk management. Past and present efforts have too often and too uncritically equated the feasible with the desirable. Results have been both frustrating and wasteful.

Another is an emphasis on the design of resilient or "soft-fail" coping strategies. The essential issue is not optimality or efficiency, but robustness to the unknowns on which actual coping performance is contingent.

The most important lesson of both experience and analysis is that societies' abilities to cope with the unknown depend on the flexibility of their institutions and individuals, and on their capacity to experiment freely with alternative forms of adaptation to the risks which threaten them.

Neither the witch hunting hysterics nor the mindlessly rigid regulations characterizing so much of our present chapter in the history of risk management say much for our ability to learn from the past.

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# I. Fear, risk, and historical perspective

At the center of the risk problem are people and their fears. Fears of loss, fears of injury, and — most of all — fears of the unknown. How we cope with those fears affects both the material well-being and the spiritual character of the individuals and societies we become.

Students of risk therefore face a number of difficulties in addressing their subject matter, and surely one of the most serious is that of establishing a useful perspective. The fears of risk are our fears, the people making and taking risks are ourselves and our neighbors. When we intellectualize ourselves away from these ambiguities, our work becomes sterile, our subjects ciphers. When we tackle them directly, our involvement makes critical interpretation impossible and broader interpretations irrelevant. Unable to see inside the problem, we trivialize it. Unable to see outside the problem, we become part of it.

I suspect that work on contemporary risks will always contain some elements of this contradiction. To better appreciate the problem we are in, to better orient our directions for the future, a backward look into the history of societal risk assessment therefore seems in order. Here, with the perspective of time, we should be able to perceive some of the pitfalls and opportunities of risk management which our intimate involvement in the contemporary scene denies us.

Unfortunately, what must have been a truly monumental environmental impact assessment on the Seven Days of Creation has been lost. But societal risk assessment nonetheless has a history as long as man's efforts to explain, manipulate, and cope with his fears and the unknown. Much of this is still accessible to us, and should have some lessons to teach. That at least is a possibility, and one that has not yet been explored.

For several years now I have been trying to convince some competent historians to undertake a retrospective study of societal risk, all to no avail. The present historical "essay" is the result, and I emphasize that I use that term in its original sense of an amateur's first attempt. This attempt has been fun, and has provided me some interesting perspectives on our present risk dilemmas. I hope its transgressions of historical fact will sufficiently outrage professionals that their rebuttals can begin the serious study which I seriously do believe is needed.

In the next three sections I review what seem to me three particularly instructive episodes in the history of social risk assessment. The European witch craze of the 16th and 17th centuries is treated in Section II, some North American experience in renewable resource management in Section III, and medical drug regulation in Section IV. The historical perspective derived from these studies is used in Section V to shed some light on the unasked question of "What are we arguing about?" in the contemporary risk debate. Finally, in Section VI, I look forward to the prospects for adaptive design of risk management policy.

# II. Witch hunts: On the social psychology of risk\*

For several centuries spanning the Renaissance and Reformation, societal risk assessment meant witch hunting. Contemporary accounts record wheat inexplicably rotting in the fields, sheep dying of unknown causes, vineyards smitten with unseasonable frost, human disease and impotence on the rise. In other words, a litany of life's sorrows not very different from those which concern us today.

The institutionalized expertise of that earlier time resided with the Church. Then, as now, the experts were called upon to provide explanation of the unknown and to mitigate its undesirable consequences. Rather than seek particular sources of particular evils, rather than acknowledge their own limitations and ignorance, these experts assigned the generic name of "witchcraft" to the phenomenology of the unknown. Having a name, they proceeded to found a new professional interest dedicated to its investigation and control.

As the true magnitude of the witch problem became more apparent, the Church enlisted the Inquisition, an applied institution specifically designed to address pressing social concerns. The Inquisition became the growth industry of the day, offering exciting work, rapid advancement, and wide recognition to its professional and technical workers. Its creative and energetic efforts to create a witch-free world unearthed dangers in the most unlikely places; the rates of witch identification, assessment and evaluation soared. By the dawn of the Enlightenment, witches had been virtually eliminated from Europe and North America. Crop failures, disease,

<sup>\*</sup>This section draws from Trevor-Roper (1), Harris (2), Duerr (3), and Summer's translation of the Malleus (4).

and general misfortune had not. And more than half a million people had been burned at the stake, largely "for crimes they committed in someone else's dreams" (2, p. 221).

How did the expert institutions of the day come to wreak such havoc on the people they sought to protect? Answers to this question provide some useful perspectives for our present attempts to assess societal risk.

Witches and witchcraft can be traced back to the very beginnings of history. For centuries, people had found "witches" a convenient label for their fears of the unknown, an adequate explanation for the inevitable misfortunes which befell one's crops, health, and happiness. For centuries, the Church adopted a skeptical and largely academic approach to these explanations, preaching the difference between fact and fantasy, and placing witches squarely in the latter category. Witchcraft, if it existed at all, was an illusion sent by the devil. These illusions were frowned upon and even prohibited by law. But individual witches and witch mongers were not sought out by the Church and, if brought to its attention, were merely advised of their errors and urged to desist. Persistent individuals were simply excommunicated. The social structure, represented by the Church, declared itself no longer interested in or responsible for the welfare of those individuals. If the miscreants chose to ignore responsible advice, their subsequent fate was their own business, and the devil's. Witches remained an individualized risk, requiring individual responses by individual members of the Church and lay communities.

Wildavsky (5) has spoken of the "watershed" which is passed when such individualized issues are collectivized under unified social policies.

Institute and Sprenger's Malleus Maleficarum (The Hammer of the Witches,

published in 1486) was for the witch hunting business that collective consciousness watershed which Kefauver's Hearings would later be for drug regulators, and Rachel Carson's Silent Spring for environmentalists. Massive in its scope and evidence, impelling in its argument, the Malleus showed that witches did in fact exist, with real power for evil. As agents of Satan, they were a heresy - a dangerous sin in need of eradication. Not individuals, but society as a whole was in peril as long as witches remained at large. Pope Innocent VIII credited this argument, and his bull Summis desiderantes affectibus authorized full application of the Inquisition, including torture, to the eradication of witches. The witch risk, to use another of Wildavsky's (5) terms, had been "socialized". Collective action by the central authority was henceforth required, and any action taken against a particular individual was justified in the name of the common good. In the case of the witch hunts, this "common good" justified the carbonization of five hundred thousand individuals, the infliction of untold suffering, and the generation of a climate of fear and distrust - all in the name of the most elite and educated institution of the day.

Modern risk assessors do not incinerate their fellow citizens. Furthermore, they seek to insure against milder forms of witch hunting by a scientific approach to gathering and evaluating evidence on risk issues. But the history of witch hunting suggests that what we say we are doing or wish to be doing in contemporary risk assessment may be far removed from what actually occurs. Again, the historical perspective may help us to recognize some of these discrepancies, and to provide a basis for their resolution.

The institutionalized efforts of the Church to control witches can be seen, in retrospect, to have led to witch proliferation. Early preaching against witchcraft and its evils almost certainly put the idea of witches into many a head which never would have imagined such things if left to its own devices. The harder the Inquisition looked, the bigger its staff, the stronger its motivation, the more witches it discovered. Similar trends have been documented in the modern literature on hazard and have long posed difficulties for those seeking to document the crime prevention effectiveness of larger police forces (e.g. 6, Fig. I-1). A general question therefore arises concerning the causal relationship between assessment and risk: Which is driving which? A strong case can be made for the notion that search effort creates the thing being sought. Since the resulting higher discovery rate of witch risks obviously justifies more search effort, the whole process becomes self-contained and self-amplifying, with no prospect of natural limitation based on some externally determined "objective" frequency of witch risks in the environment.

The way we ask questions, and the kinds of evidence we admit in our attempts to answer them, are of the utmost importance here. The Inquisition asked "Are you a witch?" and proceeded to examine the evidence to see if you were. Today, whatever we title our symposia, we ask "Is this a risk?" and proceed accordingly. In neither case is there any conceivable empirical observation which could logically force an answer "No!". In neither case is there a "stopping rule" which can logically terminate the investigation short of a revelation of guilt.

In witch hunting, accusation was tantamount to conviction. Acquittal was arbitrary, dependent on the flagging zeal of the prosecutor. It was always reversible if new evidence appeared. You couldn't win, and you could only leave the game by losing. The Inquisition's principal tool

for identifying witches was torture. The accused was asked if she was a witch. If she said no, what else would you expect of a witch? So she was tortured until she confessed the truth. The Inquisitors justified ever more stringent tortures on the grounds that it would be prohibitively dangerous for a real witch to escape detection. Of course an innocent person would never confess to being a witch (a heretic with no prospects of salvation) under mere physical suffering. The few who lived through such tests were likely to spend the rest of their lives as physical or mental cripples. Most found it easier to give up and burn.

And today? What is not a risk with a parts-per-billion test can always be exposed to a parts-per-trillion examination. If rats cope with the heaviest dose of a chemical that can be soaked into their food and water, you can always gavage them. Or try mice or rabbits. Again, the only stopping rule is discovery of the sought-for effect, or exhaustion of the investigator (or his funds). Many of the risk assessment procedures used today are logically indistinguishable from those used by the Inquisition. The absence of "stopping rules" means that both fail to meet Popper's (7) "demarcation" criterion for true science. Since neither is advancing falsifiable propositions, neither is capable of producing anything more than propaganda for its own prejudices.\*

Modern science's defense against self-delusion relies upon a spirit of open and critical inquiry. This, though hardly infallible, ostensibly uncovers errors and thereby proceeds towards objective truth. Once again, however, exactly the same high principle failed in actual practice during the heyday of the Inquisition. Within the 16th century Church, hardly a

<sup>\*</sup>On "propaganda" in this context, see Feyerabend (8). It is worth noting that both witch hunts and risk assessments also fail to meet Kuhn's weaker "puzzle solving" criterion of science (see 9).

voice was raised against the witch hunt, while those outside defended the accused only at great personal risk. After all, argued the *Malleus*, with such crop losses, child mortality, marital infidelity, and general aches and pains as exist today, "Who is so dense as to maintain. . . that all their witchcraft and injuries are phantastic and imaginary, when the contrary is evident to the senses of everybody?" Who, indeed? Only those in league with the devil. And so the few philosophers and physicians who did speak up against the hunts were themselves harassed, excommunicated, and in many instances burned along with the witches.

Today, anyone querying the zeal of the risk assessors is accused at least of callousness, in words almost identical to those used by the *Malleus* five hundred years ago. The accused's league with the devil against society is taken for granted. Persecution in the press, courts, and hearing rooms is unremitting, and even the weak rules of evidence advanced by the "science" of risk assessment are swept away in the heat of the chase (see Section IV below). This is not to say that risks don't exist, or that assessors are venal. It is to insist that skeptical, open inquiry remains theory rather than practice in the majority of today's risk debates. That those debates are so often little more than self-deluding recitations of personal faith should not be surprising.

A last insight into our modern treatment of risk evidence comes from the historical demise of witch hunting as a profession. In 1610, after a century of witch hunting, the exceptional Inquisitor Alonso Salazar y Frías carried out an extensive analysis of witch burnings at Logrono, Navarre. He showed that most of the original accusations had been false, that torture had created witches where none existed, and that there was not a single case of actual witchcraft to show for all the preaching, hunting, and burning which had been carried out in the name of the Church.

He did not rule on whether witches existed. He did order that the Spanish Inquisition no longer use torture under any circumstances, and that accusations no longer be considered unless supported by independent evidence.

The number of witches brought to trial declined precipitously.

In modern terms, y Frías had instituted a grand jury condition between accusation and trial. Further, he had introduced rules of evidence which recognized the perverse and essentially meaningless forms which unstructured "facts" could take. Neither of these reforms has yet been introduced into major streams of the contemporary risk debate. And very few retrospective studies of the sort carried out by y Frías have yet been conducted by the modern risk assessment community.\* When we realize that y Frías' study occurred only after a century of active witch hunting, and that the practice was not completely stamped out until more than a century later, the prospect of rationalizing contemporary risk assessment seems distant indeed.

It is all very well to note the psychological and evidential problems which led the Church to protect its fold by burning goodly numbers of them. But witch hunts continued as an organized political activity for over two hundred years, and it requires a certain credulity to pass off such persistence as a product of excess zeal and logical error. We may be forgiven for joining the lawyers in asking "Cui bono?": Who benefited from this complex, expensive, and destructive undertaking?

Anthropologist Marvin Harris has pointed out that to believe that the main purpose of the witch hunters was the annihilation of witches is to accept uncritically the lifestyle consciousness professed by the witch hunting community. Looking at "its earthly results rather than its

<sup>\*</sup>The invaluable studies of Lawless (10) focus on cases where a serious risk existed, but was recognized late. Missing are the complementary studies of legislated restrictions where no risk existed. I discuss some retrospective looks in the matter of drug regulation in Section IV.

heavenly intentions" (2, p. 237), the witch hunt supports a rather different interpretation. Whether individual witch hunters sincerely believed in what they were doing is not the point. As with risk assessment today, what actually happens may be radically different from what people think is happening. The benefit of our historical perspective on the witch phenomenon is that, with hindsight, we can see that difference, and try to learn from it.

To begin with, there was certainly an element of opportunistic careerism in the Inquisition, and there is almost certainly an element of opportunistic careerism in the present risk assessment movement. However small this element, it is clear that it can do a lot of damage to the world that the profession is trying to protect, and can bring the profession into disrepute in the process. The same reform Inquisitor Alonso Salazar y Frías who restructured the rational side of the witch hunt was evidently a worldly man as well. Besides instituting grand jury hearings and rules of evidence, he revoked the law that property of a convicted witch could be confiscated by the Church. The rate of witchcraft accusations in Spain dropped precipitously. It is interesting to speculate on what might constitute a similar perturbation experiment for today's risk assessors.

A second point illuminating the witch hunt phenomenon is that virtually no members of the clergy or aristocracy were accused, much less executed.\*

At best, the profession was evidently incapable of coping with findings which refracted on itself. In fact, it reacted like a powerful elite which finds its own ox is about to be gored. One assumes that heretics accusing these privileged elites were promptly identified as the devil's agents,

<sup>\*</sup>H.C.E. Midlefort (1972. Witch hunting in southwestern Germany. Stanford Univ. Press, Stanford) shows that of 1258 executions between 1562 and 1684, 82% were female. 3 members of the nobility were accused, and none were executed.

which they surely were. Anyone who has followed the recent debates over the risk of recombinant DNA research\*will recognize that things haven't changed much, and can imagine the outrage with which the Church must have reacted to accusations upon its own house. The same episode justifies a certain skepticism regarding the presumption that today's science community is willing to pursue its risk assessment activities into areas striking close to home.

A third historical issue is less firmly established but, for purposes of understanding the present risk enterprise, much more significant. Harris continues his analysis of the witch hunts with an argument that they functioned directly to increase the power of the elite institutions which conducted them, and simultaneously directed discontent against those institutions into relatively nonthreatening channels:

The poor came to believe that they were being victimized by witches and devils instead of princes and popes . . . Against the people's phantom enemies, Church and State mounted a bold campaign. The authorities were unstinting in their efforts to ward off this evil, and the rich and poor alike could be thankful for the energy and bravery displayed in the battle. The practical significance of the witch mania therefore was that it shifted responsibility for the crisis of late medieval society from both Church and State to imaginary demons in human form . . . Not only were the Church and State exonerated, but they were made indispensable. The clergy and nobility emerged as the great protectors of mankind against an enemy who was ommipresent but difficult to detect (2, pp. 237-238).

<sup>\*</sup>For a review, see P. B. Hutt. Research on recombinant DNA: the regulatory issues. South. Calif. Law Rev. 51(6): 1435-1450 (1978).

Whether valid or not, there is an obvious modern parallel to this interpretation of the witch craze. Science has been under growing attack in recent years for a variety of ills from wasting the tax dollar, to pompous arrogance, to greedily destroying our environment for short-term personal gain. The science establishment has recognized this, and governments are now funding great programs on "research applied to national needs". Individual scientists, with all the good will in the world, speak of the need for "critical science" focussed on just such needs. If professional interests such as risk assessment continue on their present course, it will not be long before science can display its difficult and unstinting efforts to ward off evil, its indispensability as "great protectors of mankind against an enemy who is omnipresent but difficult to detect". This scenario does not require venality, but only self-interest and self-delusion. Perhaps for that reason alone, it merits our attention.

To read too directly from the witch hunts of the 16th and 17th centuries to the risk assessments of the present would be to fall into the trap of historical determinism. To declare without further ado that "It can't happen here" would be to display naiveté of another sort. At a minimum as Trevor-Roper (1) has argued, the existence of the witch craze in the midst of the Renaissance is "a standing warning to those who would simplify the stages of human progress."

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The "new professional interest of risk assessment" is not necessarily a progressive step. Neither its professed rational-scientific foundations

nor its concern for collectively redressing ills of the human condition are enough, in themselves, to make it so. Both the potential for bettering human life and the potential for witch hunting are latent in contemporary risk concerns. Our pressing task is to learn how we can cultivate one aspect of this Janus-faced creature while suppressing the other. In the next section I consider some more recent risk assessment experience which illuminates further aspects of this problem.

# III. Resource management: On the function of uncertainty\*

Some particularly useful insights on the basic nature of risk phenomena can be drawn from a consideration of man's attempts to manage environmental resources. The dual character of "risk" is again apparent. The river that brings water, irrigation, and transport also brings floods. The plants and animals with which we cohabit the earth provide us with oxygen, food, labor, and a variety of more subtle benefits. Under other circumstances, they may compete with us as "pests", attack us as diseases, or inconsiderately disappear under the various demands we place on them.

There is nothing witch-like or imaginary about the risks encountered through our relations with such resources. Failure to cope leads not to the ambiguities of future purgatory, but to the definite and immediate consequences of drowning, starvation, and consumption.

Anthropological studies have shown that pre-industrial "folk" societies adjust to such environmental risks largely through modifications in human behavior. From an external perspective, these adaptations often appear mystical and arational. On closer examination, they often exhibit the virtues of being effective a good deal of the time, of being flexible and easily adapted, of requiring action only at the individual or small group level, and of imposing little stress on the environmental system as a whole (15, p. 982; see also 16, 17). Modern industrial societies have tended to pursue an opposite course of adaptation, controlling and reducing the variability of nature by means of large, long-duration, capital-intensive "engineering" projects. These have indubitably succeeded in achieving many

<sup>\*</sup>This section is based on the work of my colleagues at the Institute of Resource Ecology, University of British Columbia (11, 12), and on Ian Burton, Gilbert White, and Robert Kates's studies on man's relationships with environmental hazards (13, 14, 15).

of their short-term goals. But a look at the historical record shows that many of these gains have been bought at the expense of expensive and unanticipated long-term consequences. We have begun to discover that variability and uncertainty are in fact important "structural" factors, responsible in large part for the way our environmental and resource systems work. In general, they cannot be removed or reduced without precipitating major changes in those "workings". In particular, the control of small, frequent fluctuations has resulted time and again in a growing vulnerability to rare but large perturbations. Consider some particular examples.

Throughout the middle part of this century, the United States devoted unprecedented expenditures to the control of river flooding. By 1960, however, it was clear that the country's increasing flood control efforts were supporting an ever rising level of flood loss and damage (18). As might have been expected, there followed a great deal of acrimonious debate amongst the flood-protection industries, Congress, flood victims, and sundry academics. The facts were denied, explained away, attributed to extraneous factors, and so on. But gradually there grew a body of evidence showing that the early technological view of flood risk protection had been seriously incomplete. People, together with their reactions to perceived flood frequency, had been left out of the picture. When empoundment and levee construction made former flood plains less prone to flooding, people reacted by moving into areas which now appeared "safe enough". Good control of normal river fluctuations was indeed achieved, and the previously farmed lands became more and more densely settled, their flooding history a more and more distant reality. When an exceptional flood eventually did exceed capacity of the flood works - or, much more rarely, when those works failed under less than their designed tolerances - the floods which

resulted caused unprecedented damage (14, 18). Only now are comprehensive strategies, incorporating the human element, beginning to be devised. And these, almost without exception, are emphasizing mitigation and flexibility of response rather than the old litany of flood "control" (13).

A related phenomenon is documented repeatedly in the pest control literature. For example, in the period 1947-1974, agricultural use of insecticides in the United States increased over ten-fold. Over the same period, the rate of crop loss to insect pests rose by a factor of two (19). In American corn production, while the acreage treated for pests has risen from 1% to 52%, crop losses have risen nearly four-fold (19). Nor can we simply stop using insecticides and hope things will go back to their original variable but endurable state of affairs. Though this might be possible in some theoretical long run, the short-term implications for farmers and food supply would be devastating. We are, sadly but simply, hooked on a risk control policy which gives us little, but which we can no longer do without. The broad result of our efforts to control pest risks has been to increase not only immediate damages, but also vulnerability to future surprises. There is no simple explanation for these seemingly perverse relationships. In some individual crops the results have been better. In others the losses are in part due to changes in tillage and usage practice which accompanied the increases of insecticides. But in many well-studied cases, it is clear that man's crude efforts to eliminate natural variability in the resource system are directly responsible for the ensuing debacle.

One such case is documented by Canadian studies of the spruce budworm (20). Under natural conditions, this normally rare insect erupts into epidemics at intervals of 30 or more years, defoliating and killing a good proportion of the older coniferous forest as it does so. This forest destruction eliminates the insects' habitat, the outbreak collapses, and a

healthy, young forest grows back in its wake. But these temporal uncertainties make efficient commercial utilization of the forest impossible, and insecticides were applied successfully to control an incipient eruption in the 1950s. By preserving the forest in a mature condition — by reducing its variability — this policy also preserved the biological conditions which precipitated the eruption in the first place. Today, under the relatively unvarying conditions of insecticide "control", budworms have spread throughout the entire province of New Brunswick where they persist at medium to high densities. Continuous, expensive applications of insecticides are required to prevent an epidemic. The forest and forest industry are more vulnerable, and at greater risk, than ever before, should the control policy fail or be abandoned. The most intensive analyses of this dilemma have been unable to design remedial policies with any but the most painful withdrawal symptoms.

Not surprisingly, a number of parallels to these pest-control histories can be found in man's efforts to control human disease (11, 21). The case of poliomyelitis provides an especially illuminating example. It seems that prior to the 20th century severe cases of polio were rare. Minor infections were probably contracted by most children, producing immunity but few obvious symptoms in most. By the 19th century, however, improved living conditions and public health measures — in part introduced to combat cholera and other "unsanitary" diseases — had begun to isolate the more well-to-do segments of society from their traditional childhood exposures to various diseases. The reduced frequency of contact meant that these "diseases of cleanliness" were often first encountered in adult life, with violent or fatal results.

This growing toll of polio cases, perversely focussed on the most hygienically meticulous classes, fuelled the successful search for a

vaccine. By the late 1950s, the incidence of polio was again extremely low in the United States and an organized scheme of inoculations was reaching a very large proportion of the school-age population. Once again, however, there is some suggestion that this "control" of uncertainty and fluctuation may well have increased vulnerabilility to large-scale disaster. Today, polio has become for many a threat of the distant past. Public health officials are finding it harder and harder to guarantee that significant proportions of the population are not missed by immunization and booster campaigns. It has been suggested that the growing complacency over the "non-risk" of polio may well be leading us to conditions which could support a major epidemic. The same is true for a variety of other diseases (see 11, 21).

Obviously, public health and vaccination campaigns have done a great deal of good, and will continue to do so in the future. But the reduced frequency of disease brought by vaccination programs is invariably accompanied by increased risks of other sorts. Such alternative risk structures — not the simplistic myths of natural exposure versus ultimate eradication — should be the focus of policy discussions and analysis in each particular disease case. Such explicit weighing of realistic alternatives is not particularly in evidence. German measles vaccinations for children are a case in point. Here, in exchange for protecting small children against a relatively mild illness, we leave adults susceptible to disastrous and debilitating attacks. It seems virtually certain that a broader perspective would encourage the disease in childhood, and vaccinate only adults who have missed natural exposure in their youth. As elsewhere, however, a simplistic and counterproductive predilection for "control" per se has so far prevailed.

The unpleasant surprises historically associated with efforts to manage pest and disease risks might be passed off as special consequences of introducing exotic compounds into complex biological systems. But precisely the same sorts of unanticipated results have been encountered in apparently straightforward efforts to reduce the risk of forest fire in America's National Parks (2). Once again, initial efforts were successful, leading to adoption of the policy throughout the park system. Only later did it become clear that brush and scrub unnaturally accumulated in the absence of small periodic fires were providing fuel for conflagrations of a size and intensity never before experienced. Again, "withdrawal" from the initially successful risk-reduction policy has been delicate and expensive in the extreme (11).

A final example of the relationships among uncertainty, risk, and resource management concerns the role of genetic variation. Studies in evolutionary biology have shown that variable environments give rise to populations with substantial genetic differences in traits relevant to the populations' survival. One genetic type will be slightly better adapted to one type of environmental condition, one to another, and so on. As a result, over a wide range of environmental conditions, disturbances, and surprises, some members of the population will do relatively well. The occasional variation in the environment shifts the balance and prevents one form from replacing all the others. It is true, however, that, if environmental conditions can be kept constant, one form highly adapted to those conditions will usually do better than a mix of forms. In agriculture, this situation has led to the breeding and distribution of genetically pure crop strains supremely well adapted to the controlled (low risk) conditions of water and nutrient availability which modern farms can provide.

A sobering lesson in the risks of such strategies was delivered to American corn producers in 1964 (23). Huge tracts of land were by then planted in a single genetic strain of high yield corn. When a disease arose to which this particular strain was not resistant, a very large proportion of the crop was lost. Disaster was averted because some resistant strains were still available and could be used to replace the susceptible one. As a result of this and similar surprises, much more attention is now being devoted to the development and preservation of mixed genetic stocks in agriculture. The lower short-term yields obtainable from such approaches is judged an acceptable price to pay for the increased ability to cope with the unexpected.\*

Looking across these diverse examples of resource management experience, several common themes stand out. In each case, uncertainty or variability in the natural system was initially viewed as a source of risk/hazard. Without exception, it was assumed that removal of the variability would be an unmitigated good, resulting in reduced risk and improved performance of the resource system.

Initial successes led to optimism that the proposed management policy would be an effective one. But they also led to changes in the system itself. In each case, the existence of variability and uncertainty turned out to have played an important role in establishing and maintaining key relationships among the system components. With that variability removed, relationships shifted to accommodate the new reality: people

<sup>\*</sup>Unfortunately, it seems that we need to learn this lesson anew for each resource system. Present efforts to enhance the production of salmonid fish stocks in the Pacific Northwest seem likely to select for dangerously narrow genetic stocks throughout the system (11).

settled the unflooded flood-plain, budworms spread through the undefoliated forest, brush accumulated on the unburned understory, and so on. As a result, the decreased frequency of variation in the system was accompanied by increased vulnerability to and cost of variation when it finally broke loose from managerial controls. Management efforts had changed the kinds of risks encountered, but not the fact of risk. More often than not, management shifted the risk structure from a sort people were accustomed to dealing with to one they had never before experienced.

Failures and surprises of the sort described here have been instrumental in sensitizing managers to the internal role played by variability in resource systems. Detailed investigations have begun to tease out the mechanisms involved in this sensitivity, and to let us make use of it in our policy designs (e.g. 11). But if we have learned something about the different structures which variation and uncertainty can take, our ignorance still remains more substantial than our knowledge. It is now clear that we are unlikely to reduce unpleasant surprises in resource management merely by increasing knowledge or imposing crude "controls". Rather, we must learn to design resource management schemes so that they can better cope with the failures which are guaranteed by our ignorance and the inherent variability of resource systems. This need for designing "soft-failure", uncertainty-tolerant management policies is receiving growing attention in areas beyond resource management (24). Coupled with a concern for increased institutional flexibility, it forms the core of an approach to adaptive management which my colleagues and I at IIASA and the University of British Columbia have been exploring over the last few years (12). In Section VII of this paper, I will discuss some of the implications of this adaptive management notion for societal assessment of complex, incompletely known

risk systems. First, however, I wish to consider one more set of historical lessons, this time taken from a field in which solid scientific knowledge of risk is at its most complete.

# IV. Drug safety: The limits of regulation

The history of drug development and regulation shows the risk assessment profession at its best. The products in question are medicines designed from the beginning to combat specific ills of man and to improve directly his health and well-being. In return for their favors, medicines themselves pose risks, but of a very special kind.

First, exposure to the risk is limited to those seeking the related benefits. Second, the risk is undertaken in close consultation with a professional trained to help his patient balance personal risks, benefits, and alternatives in particular circumstances. Third, the nature of the risk itself has been carefully investigated, evaluated, and described through rigorous and sophisticated experimental investigations.

Each of these features of medical drugs should make their assessment and regulation easy relative to other risk situations. In fact, people dealing with nuclear, toxic chemical, or even traffic risks would almost certainly be thankful if even one of the properties listed above pertained to their systems. Looking at the history of drug safety efforts over the last several decades, we might therefore expect to learn something about the best that can be hoped for from risk assessments in other less mature and tractable fields.

This task is facilitated by the National Academy of Sciences' sponsorship a few years ago of a symposium with the familiar title "How Safe is Safe?" That symposium reviewed experience in the design of policy on drug development and regulation (25). Papers were presented by a variety of senior drug regulators, producers, and consumers. With the recorded discussion, these papers provide a lively review of the current debate on drug safety issues. In so doing they raise serious questions regarding the limits of risk management. I review some of these below.

The basic procedures for risk-benefit assessments of medical drugs are well established. Preliminary screening makes use of extensive information and experience on similar products. Promising candidates move on to limited trials in lower animals, intensive evaluations in higher animal forms, and finally to closely supervised clinical trials on volunteer human subjects (26). Real differences of opinion arise not regarding the logic of this basic plan but on the judgmental issue of how much, and what kind of, assurance is needed before drugs are approved for human consumption.

If a drug is approved with minimal testing to make it quickly available to those who need it, people may be the guinea pigs who reveal unanticipated side effects: The specter of thalidomide is never far in the background when more rapid licensing procedures are debated. On the other hand, efforts to approach zero risk through exhaustive pre-release testing are extremely expensive and time-consuming. New drugs are delayed in reaching those who need them, and marginal\* drugs may not be developed at all.

Dilemmas of this sort exist in most risk management situations. The drug case is virtually unique, however, in that different solutions have been adopted in different countries, providing a prospect for empirical comparisons of regulatory efficacy. The two most thoroughly exercised and extreme solutions are those adopted by the United States and United Kingdom. The U. S. emphasizes extensive, pre-market testing to mitigate the risk of unanticipated side-effects, while the U. K. promotes prompter release, relying heavily on an extensive system of post-marketing monitoring.

The explicit comparisons which have been carried out between these two approaches are in no sense definitive or free from methodological problems.

<sup>\*</sup>I use "marginal" here in the economic sense of low market potential, low profitability products. Some of these may be literally a matter of life and death to the few who need them, and pharmaceutical concerns do market some "public interest" drugs on which they will never make a profit. But one cost of regulation will always be to make some such marginal drugs not worth developing by even the most public spirited of private concerns.

With some unanimity, however, they conclude that the U. K. practice better advances the public interest (26, 27, 28). American regulatory caution is argued to be needlessly expensive, stifling of new product development, and not superior in its ability to assure drug safety. In particular, the stringent safety testing procedures instituted in the United States following the Kefauver hearings and thalidomide episode of the early 1960s are demonstrated to have been a mistake in classic risk-benefit terms (9). The clear and vociferously stated conclusion of such studies is that some more rational form of regulation, including less expensive and time-consuming assessment procedures, is long overdue for the U. S. drug industry.

But while American drug regulators and risk assessors are being condemned as overly conservative by collective social welfare studies of the sort cited above, 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 (e.g. 30). Advocates of this position cite the regulators' failures to detect risks which "could have been" detected, and their ambiguous reactions to ambiguous evidence as proof that the public safety is too important to be left to even the best of safety experts. The beleaguered regulators have accepted consumer representation on their drug review panels, without anyone being sure just what those representatives are supposed to represent. Congress has responded to the political importance of drug safety by almost continual intervention in and reorganization of FDA. Significantly, however, Congress' direct attempts at "representative" safety regulation have resembled nothing so much as Keystone Cops scenarios (e.g. DES, saccharine). And it has failed repeatedly to meet FDA's own requests for an unambiguous legislative mandate specifying what balance of risks and benefits does constitute the public good, how this is to be democratically determined and achieved.

What emerges from the "How Safe is Safe?" debate in the drug field is that, 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.

This is not to say that science, data, and rigorous analysis are irrelevant to actual decisions in drug licensing. Nor does it suggest that carefully reasoned risk assessments do not have a role to play in other fields, even when these are destined to deal in even greater ambiguities of "objective" analysis than do drug safety trials. It does suggest, and strongly, that the would-be "professional interest of risk assessment" must reconsider its basic goals, and reassess its own potential for real contribution to the public interest.

One direction which such a reconsideration might profitably explore is suggested by Joshua Lederberg's "systems analytic" contribution to the drug safety symposium cited earlier (30). He argues that contemporary safety testing procedures, even in the drug field, often resemble catechismal obstacle courses. These procedures undoubtedly do make it very time-consuming and expensive to introduce new products or proposals, but rarely has any effort been made to determine whether they actually do catch the hazards to which they ostensibly are a response. Some of the drug screening evaluations already cited in this section suggest that they often do not (e.g. 29). Furthermore, the cases I discussed in the earlier section on resource management suggest that simplistic or intuitively plausible "safety" measures may frequently increase total risk.

Lederberg concludes that we must come to treat the issues of drug regulation and management as problems of experimental design. Instead of

routine adherence to large scale screening experiments on mice, or bizarre attempts to determine cancer "causing" dosages of some agent, he calls for "creative investigations that look for problems on the basis of some theoretical rationale" (31, p. 80). It is the development of such rationales, rather than of arcane methodological treatments for eventually irrelevant data, which constitutes the central scientific challenge of contemporary risk assessment.

At a more prosaic level, Lederberg's call for an experimental design approach in drug safety regulation can be extended to the way in which we make use of experience and information that we already possess. comparative evaluations of regulatory performance referred to earlier are valuable contributions to the promotion of the public interest. On closer examination, however, they offer little useful policy guidance. Virtually no regulatory activity in any field has ever been shown to have a clean bill of health when subject to essentially economic evaluation (32). To conclude from such analyses that we need "less regulation", or "deregulation", may not be wrong, but neither is it particularly instructive. The "don't regulate" vs. "do regulate" choice is a sterile and artificial one. To begin creating effective policies of risk management, we must surely begin to view these issues at a finer level of resolution. We need carefully designed studies to show what kinds of risks our present testing procedures can catch, and which kinds of risks they let slip by. Armed with such knowledge, we could begin to determine the kinds of tasks which various post-marketing monitoring schemes can perform effectively, and the kinds of situations where intensive prerelease investigation is justified. Only when we begin to blend the results of such studies in the careful design of integrated risk management strategies will we be able to move much beyond the present unsatisfactory

state of regulation by polemic.

Finally, appropriate blends of risk assessment tactics are not likely to emerge from even the most sophistical contemplation. We will have to learn to make efficient diagnostic use of the different empirical experiences emerging in different countries under different regulatory approaches.

This brings us almost full circle to the notion of "adaptive risk management" already suggested by our historical experience in resource management. In the final section of this paper, I shall attempt to close that and other circles suggested by this survey of historical perspectives, and to suggest some general directions for future work in risk assessment.

## V. What are we arguing about?

The various attitudes towards the unknown suggested in my historical reviews were captured nearly a hundred years ago by Frank Richard Stockton in his story of The Lady or the Tiger?\*(33):

"The young man could open either door he pleased. If he opened the one, there came out of it a hungry tiger, the fiercest and most cruel that could be procured, which would immediately tear him to pieces. But if he opened the other door, there came forth from it a lady; the most suitable to his years and station that His Majesty could select among his fair subjects. So I leave it to you, which door to open?"

The first man refused to take the chance. He lived safe and died chaste.

The second man hired risk assessment consultants. He collected all the available data on lady and tiger populations. He brought in sophisticated technology to listen for growling and detect the faintest whiff of perfume. He completed checklists. He developed a utility function and assessed his risk averseness. Finally, sensing that in a few more years he would be in no condition to enjoy the lady anyway, he opened the optimal door. And was eaten by a low probability tiger.

The third man took a course in tiger taming. He opened a door at random and was eaten by the lady.

To interpret, we respond to the unknown by trying to retreat from it, or trying to comprehend it, or trying to control it. The first approach is evident in longings for return to a simpler "risk-free" life that never was. The second is reflected in the fantasy of synoptic risk assessment: Measure the requisite probabilities and trade-offs, calculate the social risk-benefit function, and the common good will have been defined. The third approach is in the tradition of professional engineering. It serves us well but, as engineers have been among the first to point out (35), has met its match and more in the complex social risk

<sup>\*</sup>Stockton's initial translation of 1884 has been questioned on several grounds, but remains the most complete version available. I have used his work for the first paragraph quoted here, but employ some of the more credible alternatives for its variant endings, following the reasoning I developed in an earlier study of the myth (34).

problems it increasingly is called upon to address.

All of these traditions have one thing in common. They set themselves in opposition to the unknown and try to overcome or control it, thereby hoping to establish a more predictable and less frightening world. The history of risk management shows the inadequacy of this approach. The unknown is not a wrinkle to be ironed out of the social fabric. The analysis that predicts the tiger will always be surprised by a carnivorous lady. Our ignorance will always remain greater than our knowledge.

Fortunately, none of this need present really serious obstacles to effective coping with the unknown. There is an alternative tradition of coping which, though virtually absent from the contemporary risk debate, has nonetheless long been a practical mainstay of successful coping for man and beast. This tradition accepts the inevitability of incomplete knowledge, seeks to accommodate rather than control the unknown, and thereby aims to coexist with and prosper from surprise. In this tradition, the "risk problem" is not uncertainty of outcome, or violence of event, or toxicity of substance, or anything of the kind. Instead, it is the challenge of coping confidently, effectively, and creatively with the surprising world around us. The fundamental question is not how to calculate, control, or even reduce risk. It is how to increase our risk-taking abilities.

Nowhere is this distinction clearer than in the questions of medical drug safety which I reviewed in Section IV. By any imaginable criteria, the complex, biologically active compounds generated by modern pharmaceutical concerns are risky things indeed. The sheer volume of production is frightening enough. Add the high proportion of that production that comes into contact with humans and you have a situation bound to dispatch a modern

risk assessor for his injunctions and press agents. In the medical drug case, however, the existence of a professional managerial framework within which these dangerous chemicals are characterized and administered and monitored makes them into risks we can afford to take, thereby improving our health and well-being. Any narrow attempt to create a world free from the very real risks posed by such chemicals would entail obviously unacceptable consequences. Moreover, since many drugs are now most valuable in roles for which they were not originally envisioned, any preemptive risk-benefit accounting would produce similarly unfortunate results. In contrast, improvements in our ability to take risks — in our knowledge of how the drugs confer their risks and benefits, in doctors' and patients' understanding of the trade-offs involved, in the monitoring and diagnosis of unanticipated (positive and negative) drug reactions — all increase our capacity to cope with disease and improve our health.

A similar emphasis on increased risk-taking abilities, rather than decreased risk per se, emerges as a strategy for coping with the unknown in a number of pragmatic fields which have tried the alternatives. Portfolio designers long ago recognized the fallacies of "risk-free" earning strategies (36). Boehm-Bawerk's Law, based on one of the most rigorous theorems in economics, states that existing means of production can yield greater economic performance only through greater uncertainty — i.e. through taking greater risks. Strategic corporate planning has been defined by one of its most successful advocates as creating the "capacity to take a greater risk, for this is the only way to improve entrepreneurial performance." (37). Most biologists, myself included, would concur with W. H. Auden's poem "Unpredictable but Providential", wishing only that we had put the central experience of our discipline so well:

. . . for the animate, to last was to mean to change, existing both for one's own sake and that of all others, forever in jeopardy. . . As a rule it was the fittest who perished, the mis-fits, forced by failure to emigrate to new unsettled niches, who altered their structure and prospered. . .

René Dubos states the biologists' conclusion more bluntly (38): "Willingness to take risks is a condition of biological success." This point is
critical to our understanding of human risk-taking. Willingness to take
risks, together with knowledge of risk-taking consequences, determines our
ability to cope with the unknown. Confidence is as important as understanding
for us to shape the future in a rational way. The real challenge for the
"new professional interest in risk" is to contribute to both.

In seeking to meet this challenge, it is reasonable to begin with the paradox of contemporary social risk history: The more we learn about risk the less confident we seem to be of our risk-taking abilities. Hence we have the spectacle of an American society which has a greater life expectancy, higher level of material welfare, and more knowledge than ever before, frightening itself into virtual catatonia, unable to mobilize the risk-taking efforts necessary for coping with the unknown. A "new professional interest in risk" which cannot bring itself to address, much less explain, such a central fact of its subject is hardly a thing to inspire confidence.

Nobody knows what makes one individual or society believe in itself while another heads for the bunkers.\* After all, Columbus was venturing into the void at the same time Institute and Sprenger were inciting witch hunters to new heights of paranoia. It seems virtually certain, however, that risk assessors' sincere knowledge-seeking efforts to identify potential dangers can undermine the very confidence which would be

<sup>\*</sup>For some provoking thoughts on the subject, see Gardner (39).

necessary for creatively coping with those dangers.

The proverbial "little knowledge" is not only a dangerous, but a frightening thing. We have already seen the workings of this in the witch hunts of the Renaissance. Authoritative and, let us presume, sincere preachers preached valiantly the dangers of witches and the devil's incredibly subtle and cunning ways of infiltrating society. In so doing, they amplified society's latent fear of the unknown, undermined its confidence, cohesion, and common sense, and thereby contributed to the public hysteria which later fueled the excesses of the Inquisition.

Today, authoritative and, let us presume, sincere scientists preach valiantly the dangers of risks and their incredibly subtle and cunning ways of infiltrating society. The Chief Counsel of the Food and Drug Administration admits "we often regulate more out of fear of the unknown than out of respect and appreciation of the known "(40, p. 123). Society's attitudes towards risks such as cancer and nuclear reactors are not readily distinguishable from its earlier fears of the evil eye.

This is not to say that today's society does not face real risks, nor to deny the real accomplishment of risk management professionals in dealing with those risks. It is to insist that the dual character of the coping problem — the need for knowing and willing — is virtually ignored in contemporary literature on the risk problem\*. Preoccupied with the knowledge aspects of early warnings and assessments, we are caught inside the risk problem and become part of it. Unable to see the relationship between our knowledge-seeking work and the fear of the unknown it may engender, our contributions to the real problem of enhancing society's risk-taking and

<sup>\*</sup>The problem is not unique to risk studies. Lindblom (41) distinguishes between the knowledge-based preferences which inform economic theory, and the will-based volitions which, together with preferences, inform political choice. In a penetrating essay on the nature of useful knowledge (42), he characterizes these two complementary forms of social evaluation as "thinking through" and "acting out".

coping abilities are correspondingly dissipated or flatly counterproductive.

The challenge of establishing a rational perspective from which to view risk problems and our interventions in them is, however, greater than merely coming to understand the relationship between fear and knowledge.

Alvin Weinberg provided the glimmer of such a perspective in his concept of "trans-science", first enunciated in a discussion of "How safe is safe enough?" for nuclear reactors (43):

Attempts to deal with social problems through the procedures of science hang on the answers to questions which can be asked of science and yet which cannot be answered by science. I propose the term trans-scientific for these questions. . Insofar as public policy depends on trans-scientific rather than scientific issues, the role of the scientist in contributing to the promulgation of such policy must be different than is his role when the issues can be unambiguously answered by science. . . When what we do transcends science and when it impinges on the public, we have no choice but to welcome the public — even encourage the public — to participate in the debate. Scientists have no monopoly on wisdom where this kind of trans-science is involved; they shall have to accommodate the will of the public and its representatives.

What is this "different role" required of the risk scientist? How is he to promote scientific knowledge without spreading social fear? How is the "will of the public" to be accommodated in risk problems? Neither Weinberg nor anyone else has proposed definitive answers to these questions, but in the last several years several lines of inquiry have been opened.

In reviewing these, it seems to me that there are two distinct if related issues at stake. One concerns the incompleteness of scientific understanding which can be brought to bear on risk questions. The other involves the conflicts of individual wills, values, and freedoms which bear on those questions.

## VI. Towards the adaptive design of risk management policy

Let us first consider the problem of incompleteness. In mature academic science, the incompleteness and fallibility of knowledge should cause no fundamental difficulties. Theories are held tentatively, contingent on new evidence. Contrary evidence and new interpretations are granted equal access to the debate. Independent experiment and peer review provide checks and balances against error and unscrupulous behavior. Of course the ideal standard is often bent or broken in practice, but in the long run, in the majority of cases, good science does seem to replace bad.\*

This is not the case, however, in what historian Jerome Ravetz has called the less developed or "immature" sciences, especially when these are applied to social problems (45). Here, a variety of factors conspire to supress tentative outlooks and to seize on incompleteness as an excuse for polarization. The result is bad science, leading to unnecessary public alarm, unjustified and ineffective regulations, and an unwillingness to undertake the risk-taking ventures necessary for coping with the unknown (46).

In part, the phenomenon can be explained in terms of a breakdown of quality control within the scientific discipline. The relative absence of established facts or criteria of competence tends to make peer review ineffective. Add the pull of a socially relevant, "public interest" discipline, and there is a real danger that the field will experience "an accretion of cranks and congenital rebels whose reforming zeal is not matched by their scientific skill " (45, p. 427). Where recognition and grant money both accrue to those making the first, loudest, and most frightening noises, where accusations of corruption, cowardice, or insensitivity

<sup>\*</sup>Unfortunately, it also often displaces the merely different. For a particularly readable and disturbing account of Inquisitorial intolerance in modern science, see Feyerabend (44).

are the most likely rewards of the careful skeptic, then the "great confidence game" portrayed by Ravetz cannot be far off.

The fault, however, does not all lie with science. Harvey Brooks has pointed out

. . . an interesting parallel between the scientist's desire to establish priority for a discovery or invention, and the politician's search for new issues on which he can make a name for himself. . . The potential alliance between individual politicians and scientists, though often beneficial, can also be dangerous because neither side is subject to the normal checks and balances of peer groups. Once a politician has staked out scientific territory for himself, his colleagues tend to stay away. At the same time the scientist is speaking in a forum to which opposing scientific views are not more or less automatically accorded equal access. The politician is free to select his own experts to develop an issue in the way that has maximum political utility to him. Truth may be only incidental. (47, p. 259)\*

Even the most conscientious risk scientist, trying to present a balanced view of a complex and uncertain issue, is likely to find his argument caricatured and polarized in such a process. Brooks continues:

Scientists inexperienced in the political arena, and flattered by the unaccustomed attentions of men of power, are often inveigled into stating their conclusions with a confidence not warranted by the evidence, and . . . not subject to the same sort of prompt corrective processes that they would be if confined within the scientific community. (47, p. 259)\*\*

While these and other problems of the incomplete scientific knowledge in risk matters are widely recognized, most responses have essentially called for a resolution through better science. This misses the central issue completely. Thus we have the 1976 Bellagio Conference on Science and Technology calling for the scientific community to "evolve and sustain new standards of scientific rigor appropriate to research in support of early

<sup>\*</sup>Brooks draws the latter part of his suggestion from the studies of Nelkin (48).

<sup>\*\*</sup>The difficulties encountered in scientists' statements to the media are similar in kind and origin, and even more sensational in outcome.

warnings and policy decisions" (49, p. 33). Or, for those with less faith in their fellow scientists, there are the science court proposals for what amounts to super-peer review (50). In both cases, the underlying assumption seems to be that rigorous science, or rigorously reviewed science, would not be subject to the incompleteness, polarization, and exploitation that characterizes risk science today. With all respect to good intentions, the historical experience of risk management\* makes this assumption hard to accept.

An alternative, or perhaps complementary, response to the incompleteness dilemmas of trans-science is provided by the growing craft of policy analysis. In a recent Science editorial on the subject, M. Granger Morgan argues

Good policy analysis recognizes that physical truth may be poorly or incompletely known. Its objective is to evaluate, order, and structure incomplete knowledge so as to allow decisions to be made with as complete an understanding as possible of the current state of knowledge, its limitations, and its implications. (51, p. 971)

Policy analysis of the sort Morgan describes is just beginning to emerge from its uninspiring past as a branch of applied mathematics. There are indications, nonetheless, that it does indeed offer a realistic and rational perspective from which Weinberg's trans-scientist can shape his "different role" in the social risk debate.\*\*

In some ways, this role seems likely to take on more the character of a jurist than a traditional positivist scientist. Policy analysis recognizes, above all else, that "the data" are always insufficient to dictate unambiguous conclusions. Rather, particular data are generated, selected, and inserted into an argument as evidence in support of a particular conclusion (52). The listener may be persuaded by the force of the argument and the strength of its evidence. But there is no suggestion that data of themselves are either

<sup>\*</sup>I would argue, for example, that risk management of medical drugs already has both the "rigorous standards" of Bellagio and the super-peer review of the science courts. The debate is none the less acrimonious.

<sup>\*\*</sup>The remainder of this section draws heavily on the concepts of policy analysis as developed by Majone (52), Wildavsky (53), and Lindblom (54). For another more systematically developed view see Quade (55).

necessary or sufficient to a given conclusion. The debate therefore shifts away from a preoccupation with "facts" and their "proof". It turns instead to the careful development of rules for the admissibility of legitimate evidence, and for the form of legitimate argument. Such rules are known to be fallible — the guilty can be acquitted and vice versa — but fallibility is accepted as an inevitable consequence of our lack of omniscience. On the other hand, careful attention to developing mutually agreed-upon rules of evidence can create that essential willingness to proceed in the face of fallibility. It has done this for drug regulation, and our health is the better for it. Attention to rules of evidence can also assure against the wilder tyrannies of self-evident "fact" where no effective peer review exists. It did this in Alonso y Frías' reforms of the Inquisition's torture and indictment procedures. Perhaps most important, formal rules of evidence constitute formal hypotheses on how we can best cope with the unknown. Viewed in this manner, they invite us to use our continuing experience in risk management to evaluate our present rules, and to suggest improvements in them. We therefore can learn from both our successes and our failures and hope for some cumulative improvement in our risk-taking, surprise-coping abilities. Contemporary risk management's inability to effect such cumulative improvements, its insistence on re-fighting all the old battles with each new risk issue, is one of the most discouraging aspects of its exclusively "fact"focussed approach.

The notion of learning from error is central to modern policy analysis, as it is to those pragmatic coping strategies of man and beast which I outlined earlier. The litany goes something like this: If knowledge is incomplete, if the future is uncertain, then mistakes and surprise are inevitable. The categorical imperative is to recognize such mistakes, to learn from them, and

to modify future actions accordingly.\*

In this view of life, rationality becomes a retrospective but still respectable concept. Since actual performance is contingent on facts unknown, futures unborn, and choices we ourselves have yet to make, the "rational" is evident only in retrospect. It is what turned out to be adapted to the conditions that occurred, and turned out to be adopted by the powers that were (52).

The problem of rational management is therefore to design self-evaluating policies which adapt themselves to the developing situation and, in so doing, cultivate the will necessary for their adoption and continuing pursuit. Such a reconstructive concept of rationality is central to evolutionary (as opposed to teleological) thinking in a number of fields (52). Its appropriateness as a guide to action has been argued in terms of social psychology (56), economic theory (57), and the purest of scientific endeavor (58). Furthermore, as Majone points out,

This explanation makes sense of behavior frequently observed among policy makers — such as incrementalism, adaptive adjustments, imitation, and "rationalizations" — which must appear to be irrational and/or dishonest in the prevailing models of policymaking. (52, p. 215)

Those "prevailing models", unfortunately, are the ones which inform a good proportion of contemporary risk management activity. The synoptic planners, cost-benefit analysts, and regulatory bureaucrats seem wedded to prospective, knowledge-presuming notions of "rationality" in policy making: "Optimal" or "best possible" decisions and decision-rules can be derived on the basis of available information. These can be implemented by virtue of their rationality (social optimality, expert consensus). Subsequent performance can be taken for granted, provided always that compliance with the rational rules is rigorously enforced.

<sup>\*</sup>It has been said that a fool makes many mistakes, while a damn fool makes only one. Over and over again.

other one that comes to mind. Michael Crozier, in his classic study of <a href="The-Bureaucratic Phenomenon">The Bureaucratic Phenomenon</a>, defines bureaucracy as "an organization that cannot correct its behavior by learning from its mistakes" (59, pp. 186-187).

Regulation by such bureaucracies has become almost synonymous with risk management in America today. From the policy analysis perspective, with its insistence on an adaptive, "error-embracing"\* response to the unknown, it therefore comes as no surprise that risk management is in trouble. More constructively, policy analysis suggests that effective, rational coping behavior may depend more than anything on our ability to design flexible, adaptive management institutions:\*\* Institutions which can respond to and learn from the inevitable surprises awaiting us. Institutions which can mobilize public will in risk-taking enterprises. Institutions which can improve our ability to cope with the unknown.

Explicit policy analysis focussed on design of alternative institutional structures for risk management has barely begun. The sterile debates over "regulate" versus "don't", "threshold" versus "not", and the like have occupied center stage and most of the wings (32). Some of the notable exceptions include Michael's (60) and Thompson's (this symposium) studies from the human behavior perspective, the comparative institutional studies I referred to in Section IV, plus those of Nelkin reported elsewhere in this symposium, the explicit policy analyses of Majone (61, 62, 63), and the applied work being done under the several banners of "mediation" (64, 65). These suggest a productive future for policy analyses of risk problems and their institutional settings, if only the debate can be turned in the constructive directions they have suggested.

<sup>\*</sup>The term is from Michael's (60) insightful study of the human aspects of Learning to Plan and Planning to Learn.

<sup>\*\*</sup>Significantly, this was also the overriding need identified by the previously mentioned Bellagio Conference on Science and Technology; see (24).

What that future will be like I am not so silly as to suggest in a paper emphasizing uncertainty and surprise. My personal favorite for attention concerns the "scale" of our risk management institutions and arrangements. There is a strong tendency today for every fear, every unknown to be met by mandatory regulation at a national or even supernational scale.

This approach might possibly be justified in a world where one socially optimal regulation could be computed in advance, or where the externalities of local risk-taking decisions would be truly national in scope and unbearable in effect. It might, in general, be justified if everyone wanted it. But in most cases of risk management, not one of these conditions is met.

An opposite extreme, less well explored, is a variation on the thousand flowers blooming approach to cultural revival. I suspect a careful policy analysis would show that maximal learning and political will could be mobilized by designing the scale of particular risk management ventures to fit the character of the risk under consideration. Thus while we might require regional scale regulation in such externality-laden fields as air quality management, we might find that much smaller scales — and therefore more, different learning experiments and less compulsion — would be appropriate in other cases.

Medical drugs, for example, would seem to present the perfect situation for experimenting with much more "local" autonomy in risk management decisions, even down to the level of the individual. My finer fancies imagine the Generally Recognized as Safe (GRAS) list of drugs being complemented by one General Recognized as Uncertain (GRAU). Use of drugs on this list might be at the user's discretion, with a full description of the known risks and benefits available for advice, but a minimum of absolute constraint. The liabilities issue would be difficult, but could doubtless be resolved with

sufficient ingenuity. Appropriate, perhaps, would be voluntary "de-socialization" of the risk in the form of an agreement not to hold the manufacturer accountable or insurance agencies liable for adverse effects. I can imagine circumstances under which I would agree to such conditions, just as I would have preferred the de-socialization of excommunication to the alternative of a witch trial.

The more general point is that to the extent that large-scale monolithic regulations could be avoided, "local" risk-taking preferences could be let run their course as experiments in risk management. Government could shift from its stressful role as incompetent regulator into a more congenial role as broker of information. Is California's (or San Francisco's, or J. Fred Muggs') approach to Laetrile working better than New York's? In what ways? Who has a third approach? And so on.

Note that the apparent ethical dilemma in fact is less than it seems.

If we <u>really</u> don't know how to manage a risk, then we're all guinea pigs.

The fight over whose expert to believe can be transposed into a contest over whose expert guessed better, and learns faster.

The challenges of helping to design alternative — even competitive — coping strategies and institutions, of evaluating and comparing their actual performances, and of redesigning adaptively in response to what is learned should be enough to satisfy the most ambitious of risk policy analysts. They might even make the future of risk management a more satisfactory endeavor than its past.

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