What textbook of logic does not point out in its preface that formal logic deals, not with how men actually think, but with how they would think if their instrument of thought were reason? How men actually think is left to the science of psychology or to unfathomable intuition in the case of women. To my knowledge, no previous thinker has gone so far as to enunciate the fundamental principle: "Decision-making is an emotional act".

The twenty-five years of my professional life have been dominated by this phenomenon. This and the fact that I seem to see the same effect in many if not most other human endeavors makes it seem worthwhile to call the phenomenon to the attention of statisticians generally. Instances in which the outcome is determined by the dominance of the emotional setting in which decision-making occurs fall into four general types of consequences. First, incidences distinguishable only by their emotional content lead to differing results, whereas had the decision been a rational one the outcomes would have been similar. Differences in sentences for the same crime but by a different accused may be the most common example. Sensitivity of a decision to a change in circumstances is a second consequence of emotional decision-making. Over the same twenty-five year period the automobile and road construction were in the driver's seat. so to speak, until some time in the 1960's, when silent spring found a powerful voice; now seeming to be somewhat muted by the necessity to obtain new sources of energy and for fuller exploitation of existing supplies.

A third major characteristic of emotional decision-making is its extreme polarity. What is heinous for you to do is unavoidable, if regrettable, when I do it. It has often been remarked that there are no wars of aggression. All initiations of hostilities are but reactions to incidents, threats, or dangerous preparations of the attacked.

It is a fourth area of emotional decisionmaking that is my chief concern. Certain topics. actions, or devices per se are inordinately highly charged emotionally. Biological warfare is such a subject. Its stigma arises from two sources. It is perverted medicine and medicine is expected to be nice. It was placed under the Army Chemical Corps and Americans think that chemical warfare was a German innovation. No such stigma attaches to the tank, even the flame thrower, for the tank was invented by the English. I cannot claim to have examined all of the discussion, but I have not seen any that explains why it is better to be killed by a bullet or a bomb than by gas or a disease. That both gas and disease may be incapacitating and not permanently injurious is of course ignored in such discussions.

So emotional is medicine generally that no activity is permitted which could conceivably have contributed to the death or injury of a person whether intentionally, negligently, or otherwise. Only in medicine and health is perfect performance demanded. Military commanders

* Scheduled but not delivered.

may be censored for reckless exposure of their men but they are never expected to win battles without losses. Physicians, too, are not expected to practice medicine without occasionally losing a patient. But the loss is to be due to the disease or disability. Every act of the physician should universally have the consequence of reducing or minimizing the consequences; never, of itself, to contribute to the injury of the patient.

Vaccine administration does not meet this test. The first large scale attempt to protect a threatened population from an epidemic by immunization--actually inoculation--occurred in Boston in 1721. The medium was not a carefully attenuated strain but fully virulent smallpox. This first extensive application of the procedure was attended by a highly emotional dispute as to its legitimacy and its effectiveness which has continued to the present in connection with the later vaccination against smallpox. But in the process the standard of performance has grown inordinately, and the nature of risk has been dramatically altered. In 1721 few if any people could escape exposure to smallpox. Today few are likely to be exposed. The relevance of this example to the topic of this paper arises on the one hand (1) from this minuscule risk, (2) from the even smaller risk of a catastrophic outbreak, and (3) from the small but still appreciable risk of untoward results from vaccination itself. On the other hand we have a government which condones a known killer -tobacco. Both questions are discussed in largely emotional contexts. And the adopted actions in the two cases differ widely while it would appear that they should be similar.

The history of vaccine introduction, like the history of food and drug regulation, and indeed every form of endeavor affecting health and safety where explicit overt action is involved has continued to be highly emotional. The highly emotional reaction to death or injury traceable to explicit overt action in contrast to the tolerance for far greater consequences of neglect or indifference has often been noted by astute critics; without in general arousing the public. For example most modernizations of applicable law have followed some dramatic occurrence, often however far less costly in the aggregate than other less dramatic, more constant, threats to life and safety. This point was expressed at the first Academy Forum of the National Academy of Science on the Design of Policy on Drug and Food Additives held in Washington, D. C. on May 15, 1973 by Peter Hutt, Assistant General Counsel for Food and Drugs, DHEW, in the words:

"In short public policy design and execution with respect to the safety of food and drugs is highly and perhaps irretrievably, controversial. It raises up a welter of subjective and emotional views that often obstruct rational analysis and that severely hinder regulation by scientific decision-making.

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"One does not need a degree in science to hold and express deeply-felt beliefs on the degree of risk or uncertainty society should accept from food and drugs. Nor, indeed, does a scientific background equip one with any greater insight into the intricacies of this type of policy issue or any more impressive credentials or greater authority to act as an arbiter in resolving these matters. As long as we remain a free society, these basic philosophical principles will, and properly should, remain the subject of intense public scrutiny and debate.

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"As a lawyer, I am not only accustomed to the adversary process but also a strong advocate of it. Nevertheless we must be careful to prevent trial by combat from replacing reasoned decision-making on important safety issues".

The words "statistics" or "statistical decision-making" do not occur in Mr. Hutt's address. Either he is unaware that a discipline of statistical decision theory exists or he rejects its applicability in safety regulation of food and drugs. Moreover the Interdisciplinary Communications Program of the Smithsonian Institution has held or is planning some half dozen conferences on the Philosophy and Technology of Drug Assessment beginning in May of 1970. The roster of attendees for the first two conferences does not contain the name of even one professional statistician though I am informed that this omission was rectified by the third conference.

The status of decision-making in activities affecting life and safety then is: (1) little use is made of formal statistical techniques including statistical decision-making; (2) discussion in these areas is highly emotional and inconsistent. One thesis of this paper is that these two characteristics are related.

The best encapsulation of the impossibility of rational decision-making when emotion is dominant and why that I have seen is continued in a letter to the editor of Medical World News for November 26, 1965. The correspondent, Dr. John T. Flynn, referring to the opposition of "regular" physicians to practitioners of psychoanalysis, wrote: "The tragic fact is that our disrespect of psychiatry and psychological theories must remain a futile posture until a solid theory of human psychological functions can be established. Unhappily, attempts to refute psychoanalytic theory run aground upon the rigidity of human faith. When a solid basis of scientific fact does not underlie an understanding of some area of nature then pure faith and belief in a system of some kind seems a human necessity. It does little good to chip away at such an unsubstantiated system by means of appeals to logic, furious attacks, or sarcasm. The only way one can displace inadequate or fraudulent theory is by offering a superior substitute based upon clear scientific understanding. The age of reason still remains an age of faith".

As averred by the Assistant General Counsel of FDA, decision-making in the regulation of food and drugs has since the beginning and is daily an emotion-stirring process. Why is that? Dr. Flynn implies that we lack the appropriate scientific basis for a rational solution. But why is that? Mr. Hutt appears to assert that the situation will inevitably remain emotional; and in doing so handicaps rational decision-making. Dr. Flynn in an analogous discipline asserts that emotion can be eliminated so soon as an effective rational explication becomes available. It is his view that I subscribe to: That is: emotional discussion is a symptom of a lack of an adequate rational base. Its disruption of rational decision-making while real and destructive is secondary.

But Mr. Hutt has highlighted the essential lack in the safety field when he writes: ". . . there appears to be no public or scientific consensus today on the risk or uncertainty acceptable to justify the marketing of any substance as a food or drug". But, of course, it is agreed that if any risk whatever is acceptable it is a very low one, of the order of one in a 100,000 or even less.

I will assume here that this is in fact the one ingredient missing to permit removing most of the emotional content of decision-making in food and drug regulation and indeed in all activities involving human life and safety. Hence the problem arises because of the very low risks which are tolerable. The currently dominant Baysean approach to probability assessment arose for the most part in the context of the socalled unique incident probability estimation, the Amchitka underground test, where nothing comparable has ever occurred in the past.

In this latter context, but applicable to both, the author has supplied an approach to the numerical estimation of very low probabilities in a previous paper entitled "A Probability Approach to Catastrophic Threat" available from the National Technical Information Service. The effect of this approach is to replace human estimates of absolute probabilities by relative estimates.

NOTE: The thoughts and opinions expressed are exclusively those of the author.