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The attached synopsis of a meeting in Colorado Springs, Feb. 15-17, 1978 on Risk/Benefit Decisions is instructive. It reflects the type of problems facing society and the regulatory process. Also, the principles, although in evolution right now, will be applicable in the analysis of risks associated with chemical hazards and related product liability concerns.

CEB:sk

C. E. Blades

Rec. 3/16/77

Symposium on Risk/Benefit Decisions and the Public Health
Air Force Academy - Colorado Springs, Colorado
February 15-17, 1978

There were 112 registered attendees at the subject conference, including 42 staff members from the four regulatory agencies jointly sponsoring the meeting (FDA, EPA, CPSC, and OSHA), 14 academics, and 16 from industry. The purpose was to consider how risk/benefit (R/B) analyses can be used to improve public health through regulation.

Most of the speakers were from the regulatory agencies and from universities. The subject matter covered scientific, social, economic, and ethical implications of R/B.

Senator Edward Kennedy, chairman of the Senate subcommittee on health and scientific research, spoke early in the first session and warned that future generations of Americans may face massive cancer epidemics because of the myriad industrial chemicals being released into the environment. American industry is making 70,000 chemicals annually, including 1000 to 2000 new ones each year. He said 6 million workers are exposed to chemicals known to have produced cancer in animals; 1 million are regularly exposed to benzene, known to be a highly potent carcinogen. The burden of proof should be on chemical makers to show that their products are safe. Recognizing that there is no such thing as absolute safety, R/B assessments, based on improved data and methodologies, are long overdue in setting regulations to protect public health.

The Senator said that risks are often treated inconsistently by the government, like banning saccharin and subsidizing tobacco-growing; this is not the fault of the regulator, but is due to special interest group pressures in Congress. The saccharin issue shows that the public, when properly informed, is ready to participate in the R/B process, and this participation is the cornerstone for successful regulation in the future.

My understanding of the most significant points brought out at the meeting is as follows:

1. There has been some limited use of R/B so far on both broad (radiation, smoking) and specific chemical (lead, mercury, vinyl chloride) bases, but it has been in an ad hoc fashion and good procedures have not been developed yet.

2. The consensus was that R/B should and will be used much more extensively in the future. This is expected in spite of (1) the advocates of zero-risk and/or (2) others that maintain that technical data and methods will never be reliable, and the moral issues are so irreconcilable that extensive use of R/B will be impractical. The Delaney clause (zero risk) was thought to be appropriate for food additives since it was hard to visualize any benefit ever great enough to offset any risk of cancer. But this is now being questioned; and it is not the case for drugs or for industrial chemicals.

3. There appears to be three essential steps before meaningful R/B can be initiated on industrial chemicals on a broad basis.

- A simple screen , type method is needed to pri ize and rank the materials for further data gathering. (The Toxic Risk Assessment Program*procedure might be readily adapted for this purpose since it provides for expert weighting of the inherent toxic properties of the material as currently known, and for evaluating the potential for escape into the environment. This procedure is described in the 1977 Manufacturing Chemists Association publication on "Symposium on the Approaching Toxics Era".)

- An acceptable analytical methodology must be developed for obtaining the needed technical data on both risks and benefits. Perhaps screening type testing might suffice for initial R/B assessments followed by more extensive longer range testing for R/B reevaluations.

- An acceptable method must be developed for dealing with moral values when balancing the two technical sides of R/B in the final decision making leading to regulations. Is it proper to place value judgments on human lives, and, if so, how does one value a known life versus a statistical life?

4. There is some agreement on the general way that benefits change with increased costs and reduction of risk (see attachment). Though progress has been made in developing probabilities of risks, there has been no weighting of the factors that make up the benefits. The "cost of abatement factor" received relatively little emphasis.

5. Regulatory approaches evolving from R/B assessments might range from banning of a product to setting a precise acceptable target level of risk (See attachment).

6. EPA appears ready to use R/B on a broad basis and will issue a new strategy for this very soon.

7. There is general agreement that the public should participate in R/B decisions, but they must first be informed of the issues in an objective "middle road" manner as opposed to the confusing and often misleading extreme news releases common today.

8. There is some strong feeling that a generic approach to regulation is the only one practical at this point; it should be uniform across agencies.

Mr. Sheldon Samuels, Director of Health, Safety and Environment, Industrial Union Department of the AFL-CIO spoke on "The Fallacies of Acceptable Risk". He stood alone at the meeting in opposing R/B; he is opposed to risk acceptability, doubts there is ever any clear cut threshold, and would support broader applicability of the Delaney clause principle.

* Limited number of copies are available from MCA.

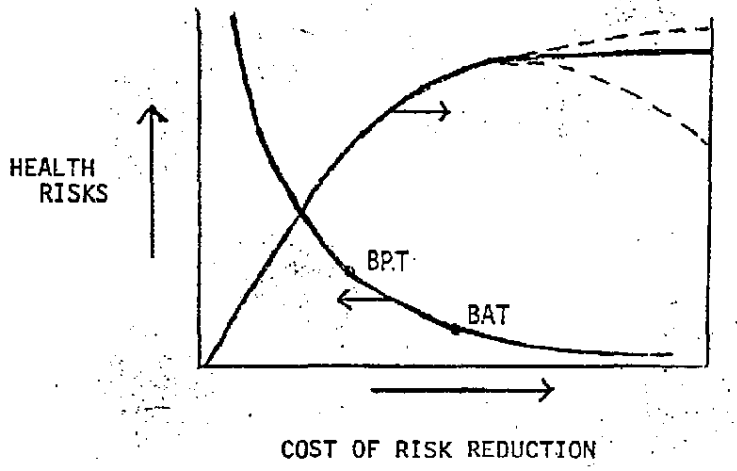
THR:mmf

ATTACHMENT NO. 1

Attendance - Total 112

FDA	18	Industry	16
CPSC	2	Academic	14
EPA	20	Media	6
OSHA	2	Consultants	8

RISK/BENEFIT/COST



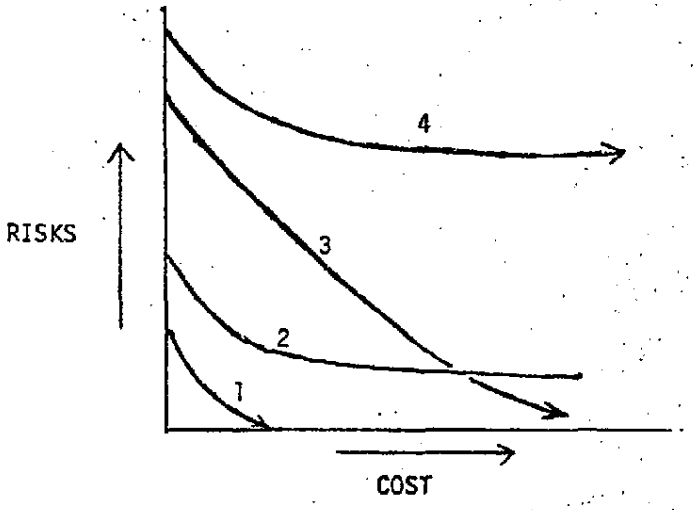
Benefits

Longer Life
Health
Employment
Environmental Quality
Income
Status
Availability Goods
Availability Services
Personal Time
Convenience

Health Risks

Premature Death
Chronic Disease
Reversible Disease
Crippling Effects

REGULATORY APPROACHES



1. Ban material - eliminate risk.
2. Set technology to reduce as much as possible.
3. Place dollar value on human life.
4. Set acceptable level of risk - to achieve regardless of cost.