THE PRINCIPLE OF ACCEPTABLE RISK

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The risk of accident and disease is inherent in life, both in advanced and in primitive civilizations. Indeed it can be argued that some measure of risk - or challenge, or even stress - is stimulating, and is essential for the balanced hormonal functioning of the body. The extreme of this is exemplified by activities such as mountaineering, motor racing, and pot-holing. A moral question arises when a man is exposed to a risk to his life or to his health in performing a task whose ultimate aim is, in the last analysis, the enrichment of society in general, or of some person or persons other than himself. Can such a situation ever be totally acceptable - and morally justifiable?

INTRODUCTION

At your last Symposium 3 years ago I spoke about industrial cancer, and mentioned briefly the Principle of Acceptable Risk. (Fourth Symposium 1971). This provoked a lively discussion, and was followed by a somewhat critical article in the New Scientist, (April 22nd 1971), to which I replied two weeks later, (May 6th 1971). This response indicated that the subject is one of general concern, and so I think that it is important for me to explain to you why it is that medical men, whose training and life-time practice is devoted to the prevention and eradication of disease, will accept a situation where men are occupationally exposed to hazards to their health, and even to their lives, so that society and others besides themselves may benefit.

There are 2 aspects of this problem:

(i) Is it right to accept predictable casualties at all?

(ii) If so, what safeguards, and what compensation, can be provided for the worker?

The most logical approach to the problem is within its historical context. This means that we have to consider the second question first, as the nature of the employer-employee relationship during the Industrial Revolution and for many years afterwards was such that the first question was never a matter for debate, and only evolved as a subject for serious consideration in recent years, as legislation and working conditions moved progressively in the worker's favour.

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Until 1880, when the Employer's Liability Act came into force, the ruling principle relating to industrial injury and disease was "volenti non fit injuria" - i.e. the workman came to his job of his own free will, under no compulsion, and so could not consider himself wronged if he had an accident or developed a disease consequent on his employment.

The iniquity of this soulless concept is exemplified by Thackrah's description of the fork grinders of Sheffield in the early years of the last century. They worked on a dry grindstone, and died of silicosis and tuberculosis at an average age of 28 to 32 - in 1822, out of 80 fork grinders, not one was over the age of 35. The machine was commonly known as the "widow-maker", and it is said that there were many women in Sheffield, still under the age of 40, who had been widowed 4 times. Miners, potters, and other workmen were similarly, though not quite so spectacularly, maimed and killed, and there was little that the unorganised worker could do about it, because of the state of poverty, and often complete destitution, of those with no work. (Thackrah (1832)).

We must, of course, present the two sides fairly. Not all the employers were monsters, and the workers were not all exploited saints. Much of the agitation for the improvement of working conditions came from enlightened factory owners themselves, such as Sir Robert Peel the Elder and Robert Owen; and only a few miles from here, in the Cheshire village of Styal, one can still see the original 18th century cotton mill of the Greg brothers, the large house in which their child apprentices were comfortably boarded, clothed, fed, and taught, and the cottages of the adult workers. Nevertheless it is true to say that by and large employers of the time were indifferent to the hardships of the workers, and the worker was helpless in improving his lot.

We have come a long way since then. The various Factory Acts, the Employer's Liability Act of 1880, the various Workmen's Compensation Acts of 1897-1945, and finally the National Insurance (Industrial Injuries) Act of 1946 were all designed to improve working conditions and to recompense the worker for industrial injuries and diseases. But legislation has its limitations - you can improve safety precautions, compensate the worker when things go wrong, and punish the negligent employer. But you cannot legislate for moral and ethical issues. What law will make an employer <u>think</u> differently, and recognise that besides his legal obligations for the health and safety of his employees, that it is in fact <u>wrong</u> to expose them to any needless or avoidable hazard?

Such a changed attitude of mind can only develop in conjunction with changes in the relationship between management and men, with each becoming more involved with the other, acquiring a greater understanding of each others problems and manner of thinking, and recognising the nature of the conflict between them.

I believe that this attitude of mind began to develop seriously soon after the last War, and it has been gathering momentum all the time. More and more companies, large and small, are being advised by specialised doctors and safety experts, not just to protect themselves against litigation, but out of a sincere belief in, and acceptance of, their responsibility for the health of their employees. The legislation which was stimulated by the earlier exploitation of the worker made the employers look at the problems of industrial accident and disease; made them see the physical plight of the sufferers, search their consciences, and act responsibly. This process has advanced so far that in many instances employers themselves have taken the initiative in the detection of the hazard, and have laid down standards at work which have preceded legislation by many years.

The Dyestuffs Industry affords a good example of this. By the 1940's it had been known for many years that there was a hazard of bladder tumour, but it was very difficult to find out precisely which were the carcinogenic agents. The Association of British Chemical Manufacturers in 1948 created a Research Fellowship at the Chester Beatty Institute in London, and appointed Dr. (now Professor) R.A.M. Case to it, to establish which were the carcinogens. The researches of Case and his co-workers took many years, but by 1954 they were largely complete, and they had identified benzidine and β naphthylamine as the main carcinogens. Meanwhile, in 1953, Scott and Williams, (Indust.Med.1957), the Medical Officers of Clayton Aniline and I.C.I., drew up a Code of Practice which was circulated to ABCM members. Although entirely voluntary, the Code was extremely rigorous, and a company violated it at its peril. It was not until the Carcinogenic Substances Reg. of 1967 became law in 1969 that legislation caught up with the entirely voluntary restraints which the Dyestuffs Industry had placed upon itself.

The Asbestos Industry has shown a similar sense of responsibility. Once the nature of the various hazards became clear (much of it due to research carried out by medical men and hygienists employed by the Asbestos companies), they led the way in the campaign for safe working conditions, and they have shown that even the stringent provisions of the Asbestos Regulations of 1969 can be complied with.

Granted this, that nowadays most employers are responsible men, with a real concern for their workers' welfare, we come to the fundamental question - to what measure of risk is it reasonable to expose a man, and what criteria should we adopt in assessing this risk? At what point may an employer feel, without smugness or complacency, "I am satisfied and clear in my conscience that, from my own observations and from expert advice, my workers are adequately protected"? It is, I think, fair to answer this question in relation to the ordinary everyday hazards which we accept as part of our lives - crossing the road, riding a bicycle, travelling in a car, train or plane, repairing an electric iron, boxing, and - most controversial of all - in smoking. It would be absurd to demand a standard of safety so rigid that the risk would be nil, in a world where everyone is surrounded by hazards all the time. True, we could stop making dyestuffs; stop using asbestos; dispense with the use of lead and cadmium and beryllium, and do without X-rays. We can survive without isocyanates and epoxy resins and agricultural pesticides, but the quality of our lives would be the poorer for doing so, as they would be if we returned to horse travel, discarded the use of electricity and banned the spirit of adventure in climbing and in pot-holing.

In fact, the clock cannot be put back, and so we must ensure that as few as possible suffer to the minimum extent. The standards which are adhered to by most enlightened companies, and which I described in my talk 3 years ago are:

1. A dangerous substance must not be used where a safe, or at least a less dangerous, substitute is possible.

2. When this is not feasible, the dangerous substance should only be used when every precaution is taken to reduce the risk to the very minimum.

3. This minimum must be so low that the chances that an instructed workman using all the preventive measures will be affected are practically nil.

4. The search for a safe substitute must always continue.

5. The workman must always be told of the nature of the hazard, and euphemisms must not be used. If the risk is of cancer, the word must be used.

There should be no distinction between the precautions taken for a cancer hazard and for the hazard of a non-cancerous industrial disease or injury of similar severity. When dealing with relatively slight diseases or injuries the standards need not be so rigorous - one cannot compare the disaster of mesothelioma due to asbestos with say, the effects of exposure to T.D.I.; or the development of bladder tumour with that of dermatitis.

To return to the more dangerous hazards. It may be thought that 3 is over-ambitious and unattainable. Let us then examine the working conditions in a modern dyestuffs factory, where the hazard - papilloma (wart) and cancer of the bladder - is such a serious one, and the incidence of which in the past was so high.

There is a pre-employment examination of the worker, and in his first two weeks of training he is informed by the Medical Officer of the precise nature of the hazard, the word 'cancer' being used. He is carefully instructed in hygienic working, and wash-basins, showers, and baths are provided, and used each according to the nature of the job. Precautions to be taken before eating and smoking are emphasised. The company has its own laundry. The worker is provided with a complete set of underclothing and outer clothing before he starts his day's work and changes into his own clothes before leaving - to ensure that no man leaves the factory carrying on him any chemical with which he has been working. Appropriate protective clothing and eye protection are used during working, and their use is insisted upon. In the rare event of spillage a strict decontamination drill is enforced.

No major carcinogens are used. Suspect substances are treated as if they were major carcinogens, and the processes are segregated from other workers. General and local ventilation is good, and as far as is technically possible the process is enclosed, with no or minimal handling. The atmosphere is regularly monitored, and the worker himself is monitored by frequent specialised examination of the urine, e.g. for aromatic amines.

It is difficult to be absolutely certain how effective are the precautions taken, because there is a latent period, averaging 18 years, - with a considerable scatter from the norm - between the first exposure and the first appearance of symptoms. Moreover, over 90% of deaths from these tumours occur in people with no occupational history at all. Nevertheless one can judge the trend and reach certain conclusions. In the 21 years since major changes in safety precautions were made in our factory, there has not been a single case of a man first employed within these years who has developed a bladder tumour. On the other hand new cases do arise from time to time in men who were first exposed in the 1930's and 1940's. Bearing in mind the average latent period of 18 years, which means that many cases do occur after a shorter time, it is felt that the hazard is under control, and without undue complacency, can be kept so by careful control of any new substances which may be introduced.

How many cases, then, would it be fair to anticipate - men who, if they had not worked in the Dyestuffs Industry, would not have developed a bladder tumour? In the light of present day knowledge (which must be the yardstick), and the above figures, I would say at most, one in the rest of this century.

Let us compare this with the risk, say, to a company driver, which everyone accepts without further thought. A few years ago a driver was asked to attend the works at the end of a Christmas party, to take home anyone who felt he had exceeded the legal limit of alcohol. No one called on his services, but on the way home, he, the driver, was killed. No one would conclude from this that the correct procedure in future is to bar the practice of arranging for a driver in these circumstances. It is remarkable how everyone - society, industry, unions, will accept road casualties (8,000 deaths and innumerable maimings) with relative complacency; but let there be a mouse death from cyclamates; a methaemoglobinaemia from toluidine, and the indignation is boundless. Somewhere between these two attitudes lies the balanced approach.

Let us now compare the bladder cancer hazard with an ordinary life hazard to which a large section of the public is exposed - smoking. It is incontrovertible fact, and common knowledge, that a cigarette smoker has a high risk of developing lung cancer (the Registrar General's figures for 1971 show a 10:1 increased incidence of lung cancer in cigarette smokers, compared with non-smokers, both in cities and in rural areas). Less well known is the increased incidence of bronchitis and coronary artery disease. There is even an increased chance of developing bladder cancer - β naphthylamine has been detected in cigarette smoke - and it has been estimated that a cigarette smoker has a bigger chance of developing bladder cancer than a non-smoking dyestuffs process worker, working in a modern factory, and adhering strictly to the Carcinogenic Substances Regulations of 1967 (London H.M.S.O.).

It is disheartening - and at times almost ludicrous - to consider how much time, money, and endeavour goes into the effort to reduce our occupational hazard from almost nil to virtually nil, while tobacco companies are allowed to advertise, in subtly suggestive ways, the use of a highly potent carcinogen, and to invite non-smokers to become addicted to the breathing of material containing this and perhaps other dangerous substances. Inspection of factories to ensure that all possible precautions are taken is both necessary and welcome; but there appears to be an inherent, almost Gilbertian, absurdity in government inspectors and doctors checking the most minute and meticulous precautions taken to avoid the risk of cancer, while their salaries are paid partly out of the revenue from tobacco taxes. Is it consistent to say that it is wrong for a dyestuffs company to benefit from the infinitesimal risk to its workers, while the tobacco companies, the government, and the advertising media wax fat on a far more considerable risk? The concern of some newspapers about industrial safety - welcomed, may I say, by most companies - would appear a little more sincere if they imposed a ban on tobacco advertising in their pages.

We have to accept that certain occupations - even certain houshold activities, such as using an electric iron, frying chips, and painting the ceiling - do carry with them hazards. Doctors and nurses may catch tuberculosis, jaundice, or other infective illnesses, construction workers and taxi drivers are liable to accidents. Provided all care is taken to prevent them; all measures are available to treat them; and adequate compensation is obtainable, those occupational hazards which approximate in their incidence to every day hazards are, I submit, acceptable. Even the ILO states that "for those carcinogens for which there are no effective substitutes, a socially acceptable risk may have to be taken". (Geneva Jan.1972 Report).

A company which is considering the use of a new chemical or a new process will often ask its medical officer for guidance on the hazards and the ways of overcoming them. Sometimes he can give practical information - e.g. the L.D.50 - i.e. the lethal dose which will kill 50% of experimental animals; but the extrapolation of this to human beings is often difficult and may be

misleading. Yet such phrases as "reduce the risk to the very minimum" and "The chances are practically nil" may strike practical scientists as being woolly and not particularly helpful.

I think that here you will have to accept that dealing with disease and with persons, is not the same as dealing with chemical reactions and with explosion possibilities, and that accurate prediction is sometimes a very difficult, and indeed, an impossible matter. The same two chemicals exposed to one another under exactly similar conditions for the same length of time will always react in the same way; but different human beings will produce widely different reactions to exposure to the same carcinogen (or to the same toxic substance such as lead or cadmium) under identical working conditions. In the days before the danger was understood, men were exposed to powerful carcinogens for an enormous concentration/time factor, and yet many did not develop a cancer and lived out long lives, and died of something else. How are we to measure the effectiveness of our precautions when over 90% of bladder cancers are non-occupational? Sooner or later a case will arise, in an exposed worker or former worker, and we will have to form an opinion as to whether it is, or is not occupational, and whether it indicates some failure in our preventive measures. Since the numbers are so few, we will be unable to make any worthwhile comparison with the unexposed population.

Individual reactions and sensitivity (which may be determined by a wide variety of factors both genetic and acquired) are so variable and imponderable that there may be no accurately fixed pattern. When you are dealing with a vast population - e.g. in studying the effects of tobacco - the margin of error is far less and the reliability of the statistics is increased. When the cases are almost single ones, one has to take a view, which might offend you as exactitudinarians, but you have to appreciate that medicine is not, as yet, an exact science.

You may, therefore, get an answer from your medical officer along these lines "I cannot give you a figure, a percentage, which is reliable. I <u>can</u> give you the feeling of informed and up-to-date medical opinion, that, say, phenyl β naphthylamine is safe to use provided its β naphthylamine content is below 0.1%; that M.O.C.A. is still under suspicion, but as the years go by and the American manufacturers still report no cases among their employees it becomes more and more likely that if it is carcinogenic it cannot be powerfully so, and so using strictly the precautions laid down in the Carcinogenic Substances Regulations should ensure safe working". If you try to push us further than this, you drive us into guessing, and so into unreliability as advisers. The weight that you attach to such opinions will depend on your confidence in the doctor's judgement, and a doctor of mature judgement will always err on the side of safety.

The layman must be particularly careful not to be stampeded by reports of doubtful origin. A lot of work is published, in journals of little importance, by authors of doubtful merit. A man of little experience, working in the University of Oswaldtwistle, may write a paper that is published in the Trumpington & Ramsbottom Gazette, to the effect that substance X, which has been used in industry for 30 years with no apparent ill effect, will, if injected in vast quantities into the abdominal cavities of pregnant rats, produce malformations of some of the foetuses. It is regarded as newsworthy by a national daily - whose crocodile tears over industrial disease we have already lamented - and soon we have a Television Programme, with a carefully loaded selected audience crossexamining and heckling the one company representative invited. The nation is up in arms - the wicked companies are making money, and poisoning or maiming us all. Then suddenly, the balloon bursts,

it is dropped by press and television with a dull thud. Whatever became of all the mercury that was poisoning our seas and rivers? Has anyone extracted it, because we never hear it mentioned now? What of the mercury and cadmium in our food, the subject of so much sensational debate? "There is no evidence of harm to health from present levels of mercury and cadmium in food for the average consumer". (Supplementary Reports H.M.S.O. - Toxicity Subcommittee). This is borne out by the 3rd Report, 1973, of Working Party on Monitoring of Foodstuffs for Heavy Metals, which states that mercury organic and inorganic and cadmium are both well within safe levels. (H.M.S.O.1973). Transportation of dangerous chemicals - normally safely accomplished with only minimal mishaps - has also received "the treatment", as has dumping of toxic wastes.

It is right to raise these matters, but too often they are presented melodramatically, with totally wrong emphasis, so that what may well be a blunder by a single company is made to appear to be the practice of the industry as a whole. Scientifically trained people such as yourselves should try to assess the credibility of what you see and hear, and discuss it with someone who has special knowledge of the subject. You might then be quoted the case of isoniazid - a most valuable drug used in the treatment of tuberculosis - which was found, after it had been used extensively in man, to cause tumours in mice. Had this been known at the outset it might well have been barred from human use, and yet as far as is known there have been no human cases at all. Even had there been a small number of cases, as the I.L.O. has commented "drugs that are carcinogenic may still be used, provided that a balance of benefit and risk can be evaluated". (International Labour Office, Geneva Jan. 1972). We must be careful then not to bar chemicals which are valuable in medicine or industry on insufficient - or maybe even loaded - evidence, presented at times by people whose competence is not certain.

The Principle of Acceptable Risk is, of course, only a concept - it has not the precision of, say, the Principle of Archimedes. It cannot be defined rigidly, as there are too many variables which affect its scientific application - e.g. the quality and commonsense of the worker, the danger inherent in the job (you cannot compare a miner with a clerk, or a window-cleaner with a locker-room attendant), and the severity of the risk (death, major disablement, minor disablement). However, if one excludes the extremes - i.e. the most and the least dangerous occupations - one can broadly say that an acceptable risk in industry is one which is of the same order as that to which people are normally exposed in their private lives in the home and in the street.

This may not be calculable statistically - how accurate can the figures of accidents in the home be? - but a stage is always reached when public concern demands action, i.e. when the Principle of Unacceptable Risk is brought to bear. Public concern can be a sensitive monitor, but in those areas where it may not operate quickly enough, control is exercised by Governmental supervision, in the form of the Factory Inspectorate, by the alertness and integrity of the doctors in the industry, and by the sense of responsibility of the management.

As an indication of what can be achieved in toxicological control, the statistics of accidents on farms in the U.K. in the past 4 years are instructive. (Barnes (1973)).

	1968	1969	1970	1971
Tractors and Falls				
Deaths	56	61	54	51
Injuries	2016	2149	1746	1672
Pesticides				
Deaths	0	0	0	0
Injuries	18	10	23	15

It will be noticed that there have been no deaths from pesticides in the past 4 years. In fact there have been no such deaths for the past 20 years, in spite of the highly lethal properties of many pesticides.

The gradual reduction in fatal and serious accidents is shown by the following figures for all industries in the United Kingdom. (H.M.S.O. Annual Reports 1970, 1971, 1972).

	Non-fatal	Fatal
1969	322,390	649
1970	304,595	556
1971	268,832	525
1972	258,137	468

This improvement in safety, which must be maintained, has not been achieved cheaply or by accident. It is the result of interest, effort and the expenditure of great sums of money. The chemical industry in particular has a great deal to be proud of in its approach to health and safety. Yet it seems to present a wrong image to the public. It seems to be always on the defensive, when it should be putting its case forcibly and fairly. If mistakes have been made - and they are in all aspects of life - they are not due to indifference, and they have been severely paid for. Men who work for a responsible chemical company can feel satisfied that every effort (much of it behind-scenes and not publicised) is made to ensure their safety, and that the risks they face are no worse than most, and better than many, that they would meet with in any other sphere of life. This is the basis of the Principle of Acceptable Risk, and it is the justification for its adoption.

SYMBOLS USED

β = beta

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