

27th October 1976

CIGARETTE SMOKING AND CAUSAL RELATIONSHIPS

The public position of tobacco companies with respect to causal explanations of the association of cigarette smoking and diseases is dominated by legal considerations. In the ultimate companies wish to be able to dispute that a particular product was the cause of injury to a particular person. By repudiation of a causal role for cigarette smoking in general they hope to avoid liability in particular cases. This domination by legal consideration thus leads the industry into a public rejection in total of any causal relationship between smoking and disease and puts the industry in a peculiar position with respect to product safety discussions, safety evaluations, collaborative research etc. Companies are actively seeking to make products acceptable as safer while denying strenuously the need to do so. To many the industry appears intransigent and irresponsible. The problem of causality has been inflated to enormous proportions. The industry has retreated behind impossible demands for "scientific proof" whereas such proof has never been required as a basis for action in the legal and political fields. Indeed if the doctrine were widely adopted the results would be disastrous. I believe that with a better understanding of the nature of causality it is plain that while epidemiological evidence does indicate a cause for concern and action it cannot form a basis on which to claim damage for injury to a specific individual.

In the Surgeon General's Advisory Committee First Report the question of causality is raised. They recognised the difficulties but agreed that causal significance of an association is a matter of judgment and noted a number of criteria which may be utilised together, not one of which alone would be sufficient, e.g. the consistency, strength and specificity of the association, the temporal relationship and the coherence of the association. They considered characterisation of the assessment of an association as a "factor", a "determinant" or a "cause". They recognised "factor" as a source of variation but not necessarily as a cause. Further there can be co-existence of several factors required for the occurrence of a disease but one factor may play a determinant role. The word cause was held to convey the notion of a significant effectual

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relationship between an agent and an associated disorder in the host. All the members accepted a multiple etiology view of biological processes. In the end they defined "cause" merely to confirm their convictions.

The Surgeon General's Committee had such great difficulty with the problem of causality because the tests for causality we "instinctively" adopt are those of necessity and sufficiency spelt out by J.S. Mill⁽¹⁾ whereas epidemiology requires - as the Committee demonstrates in practice - different treatment. It is my thesis that the tests of Mill (which I will call tests for special causality) apply only to mechanistic systems whereas epidemiology, for example, requires a probabilistic approach.

In the nineteenth century it was assumed that every effect must have a cause. To prove that A caused B it would have to be demonstrated that event A precedes event B and that event A is both necessary and sufficient to ensure that event B will follow. The view of science itself was mechanistic; it was felt that if everything was known about a system then the future of that system would be predictably certain. Within its limits this concept is still valid. In spite of appearances the behaviour of billiard balls is entirely predictable and, given the data, is calculable. This concept still dominates legal thinking. Although the extension of contributory negligence increasingly recognises multiple causes the concept is nevertheless mechanistic - there is an underlying assumption that, given the facts, the results are predictable, calculable and legally apportionable. This mechanistic concept of causality is still also the popular concept. In the modern world of advertising even the most complex systems imaginable (human emotional situations) are presented as predictably controllable by simple events such as using Brand X.

Julian Huxley in 1958 wrote "The conclusion to be drawn from the evidence is definite: increased smoking increases the probability of developing lung cancer. Unfortunately the significance of such a statement is not clear to many people. Obsessed by the naive idea of finding a single cause for every effect, they shake their heads and say that the evidence is only statistical, as if that invalidated it. In point of fact, every scientific law is statistical, and all that physicists can tell us about electrons within the atom is the probability of their occupying any particular position".

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Thus Julian Muxley began to spell out a probabilistic view of causality (which I will call general causality) based on twentieth century science. When we have a science which embraces the uncertainty principle - the unknowability of the total data for some systems - and probability to describe the properties of large populations then we cannot expect special causality to be very useful. However, just as Newton's Laws are true enough for everyday experience and relativity would be superfluous the tests for special causality can still be applied to very simple unified systems. But for complex systems involving the properties of large numbers experimentally established relationships may be used to predict the behaviour of the population with accuracy.

For example from the evidence we have that smoking is a factor in multiple correlations and is strongly associated with some diseases, this may be sufficient to substantiate a claim that smoking is a cause of the disease or causes an increase in the incidence of the disease. If it can be reliably predicted that if smoking is decreased in a population so will be the incidence of this or that disease then smoking is a cause in the general or probabilistic sense.

But the evidence obtained from populations is not relevant to the individual - as far as the individual is concerned general causality has no validity and it would be quite improper to imply predictability. And this applies to the legal question "Could smoking have caused damage to this man?" as well as to the question "Did this brand do this to this man?"

In an individual case, to prove an agent is a cause for an effect one must fall back to establishing that the particular agent was for that individual in all his special circumstances both necessary and sufficient. But these special circumstances include genetic constitution, abnormal phenotype or genotype, social status, exposure to other known agents (e.g. carcinogens) together with a host of relevant considerations. Diseases in fact are not caused merely by the presence of a particular agent. If such a simple cause were assumed then there is a necessity to explain why it only occurs in a minority of "susceptible" individuals.

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In summary, for social policy purposes it is sensible and totally relevant to use the experimental evidence pertaining to large groups and also to select the simplest hypothesis. It may therefore be concluded that for certain groups of people smoking causes the incidence of certain diseases to be higher than it would otherwise be. But no valid conclusions may be drawn from the epidemiological studies with respect to any particular individual. In this case, at present, there is no way of knowing or of calculating the probability whether smoking will cause disease in any specific individual or whether by giving up smoking he will avoid disease. Thus I find it completely consistent both to accept that the evidence demonstrates the need for some action on smoking as a social problem and also to reject a message to the individual smoker that "smoking causes lung cancer", etc.

Footnote

1. Mill was concerned to establish methods employed by scientists, methods of induction, which would act as an independent check on mere observation:
- a) If two or more instances of the phenomenon under investigation have only one circumstance in common ... this is the cause.
 - b) If an instance in which the phenomenon occurs and an instance in which it does not occur have every circumstance in common except one, that one only occurring in the former, this one differing circumstance is the cause ... (or an indispensable part of it).
 - c) If two or more instances in which the phenomenon occurs have only one circumstance in common, while two or more instances in which it does not occur have nothing in common (save the absence of that circumstance) the circumstance in which alone the two sets of instances differ is the cause.
 - d) Whatever phenomenon varies in any manner whenever another phenomenon varies in some particular way, is either cause or an effect of that phenomenon or is concerned with it through some fact of causation.

Mill was never clear whether his methods were of discovery or of proof but they did influence the approach of experimental scientists. Nevertheless his inductive method necessarily assumes that every event must have a cause.

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M 506

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22nd October 1976

SAFETY EVALUATION OF CIGARETTES

The evaluation of safety of smoking or of cigarettes is imposed on two main bodies, the cigarette manufacturers and the public authorities. It might be said that such an evaluation is entirely the responsibility of every adult smoker and for the manufacturer this is a tempting proposal. But if this view were to be sustained then cigarettes would have to be regarded entirely differently from most other items - agro chemicals, cosmetics, food additives, motor cars, etc. In any case this argument merely transfers the onus of decision - guidance on the evaluation would still be required from manufacturers and public authority. It is unlikely then that the cigarette manufacturer can avoid involvement with safety evaluation and it might be helpful to look at the factors involved.

Safety is not a measured or indeed a measurable factor. Safety is best defined as the degree to which attendant risks are judged to be acceptable. And risk is the probability and probable severity of harm - which is measurable. Because it is measurable the evaluation of risk is susceptible to a scientific approach. Judging or evaluating safety (the acceptability of risk) however is a normative, political activity and is not therefore susceptible to a scientific approach. It is to be expected then that there will be wide variance in safety judgment between, say government and interested industry or between one well informed smoker and another. There should not be - and in truth there is not - as much variance of the views on risk between scientists whether in industry or public service.

As far as smoking is concerned there is much confusion caused by scientists and particularly by doctors becoming emotionally involved and making judgments in the political area where they may not be competent. On the other hand politicians and industrialists venture into the scientific area of risk where they may be clearly incompetent. The position is not helped by some doctors belief that they are trained to be competent in both areas. Whereas, in my judgment, their general training quite properly leads them to preoccupation with individual (i.e. unique) decisions and away from both social or scientific generalisation.

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But even in the risk area the position is not clear cut for smoking. In spite of the general similarity in the results of various epidemiological studies there are no precise measurements of the various risks involved in smoking. There is also considerable scope for different interpretations of data and some fairly formidable problems with self selected samples in epidemiological studies. Thus although the evidence on which risks of smoking may be estimated is well known, perhaps the only conclusion supported by all scientists is that the risk is above zero.

When it comes to safety evaluation, although it is true that the same sort of factors are involved whether judgments are made for social or business purposes, when presented with a variance in risk probabilities industrialists are justifiably inclined (at least publicly) to choose the lower and those held responsible for public safety similarly to choose the higher risk. There is thus an understandable and justifiable divergence in the evaluation of the safety of cigarettes. In a highly civilised society it is in the interests of all to aim to get these evaluations to converge. This can be done by 'more research' to get closer agreement on risk. However, value judgments must still be made and it may be worthwhile indicating some of the factors which are involved in making such judgments. One factor is concerned with benefits - and it must be made clear that benefits are value judgments. Scientific research can indicate efficacies in achieving measurable results but it cannot indicate or measure benefits.

The sort of questions which must be asked are as follows:-

- Is the risk voluntary or involuntary?
- Is the effect immediate or delayed?
- Are there alternatives?
- Is the risk known with certainty?
- Is the exposure essential?
- Is the risk encountered occupationally?
- Is the hazard common or "dread"?
- Does it affect average people or sensitive people?
- Will the product be used as intended or is it likely to be misused?
- Are the consequences reversible or irreversible?

We are thus concerned with considering, as well as risk, social cost, custom, reasonableness, best available practice, benefits etc., and in making a decision these several or many components must be appraised, compared and

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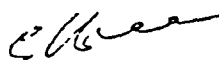
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weighed against each other.

The difficulties in food safety evaluation are similar to those for cigarettes. There are considerable differences in judgment on food and it is to be expected that there will be wide differences in the judgments of smokers, politicians, and industrialists.

The cigarette manufacturers, in my opinion, are entitled to say: "As long as there is insufficient consensus on risk (but not until there is clinical proof of the mechanism) we are not able to make useful safety judgments" - this is in effect the tight rope. Coupled with my previous argument on general (probabilistic) and special (mechanistic) causality which enables the manufacturer to say, even if there ever is consensus on risk, this can only be construed as a general causal relationship applying to the incidence of disease in populations and is not applicable to any unique individual these are very effective defensive P.R. and legal positions. Coupled further with support for research, a recognition that this only can establish (or reduce) risk etc., and that in the end safety, benefits, fairness and balance are all value judgments our public position is logically quite respectable. If at the same time we recognise that those with wider responsibilities to the public are entitled to make different value judgments with respect to the acceptability of risk and the loss of benefit and to act on them, I believe we have the best public position obtainable in the circumstances. In summary this is -

- (a) Risk is the business of science and there is not consensus.
- (b) Safety is dependent on value judgments and wide differences are to be expected.
- (c) More research at all levels should help evaluations to converge.
- (d) While there is evidence that smoking is associated with higher incidences of some diseases and general causality may be claimed, special causality can never be proved.
- (e) The slogan is informed responsibility - of adults governments and industry.



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