

PROJECT EMNMeeting held in Millbank, July 25th, 1986

Present : Mr. J.L. Mercier)
 Mr. C. Warren) - Imperial Tobacco
 Dr. P.J. Dunn) Canada

Mr. R.J. Pritchard - Brown and Williamson

Mr. E.A.A. Bruell)
 Mr. N. Davies) - BATCo.
 Mr. A.L. Heard)
 Dr. R.E. Thornton)

1. BACKGROUND1.1 Rationale

There are many constraints operating on the tobacco industry in 1986. For example, as a result of the anti-smoking lobby, taxation is increasing and consumption is falling, and young smokers are declining in number. Politicians are not unhappy with these trends. Issues related to Product liability also constrained the industry and all such issues related to Smoking and Health.

1.2 Opportunities

If we could remove Smoking and Health pressures' the industry would stabilize and then grow.

1.3 Objective

"To work towards the discovery of a 'safe' cigarette, 'safe' in the eyes of those who say that the current cigarette is 'unsafe'."
 [Business-oriented, not research oriented].

1.4 Business Aspects

- (i) Any return on an investment that led to an increase in smoking should be high.
- (ii) The potential complexity of the project made it difficult for [non-tobacco] competitors to enter.

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1.5 Strategy

Briefly the project is related to a programme of research related to a three tier approach:

1. Eliminate [undesirable chemicals] and test for biological activity
2. Modify [the cigarette]
3. Neutralize [by vitamins etc.]

which in turn relate to four research areas:

1. Chemical Needs
2. Biological Tests
3. Epidemiology
4. Mechanism of Disease Production

2. DISCUSSION

- 2.1 It was accepted that the world-wide scenario on Smoking and Health was not greatly different to that in Canada. The importance of variations in the economy of individual countries was stressed (e.g. recent increases in consumption in Denmark), as was the role of drugs in societies where smoking was discouraged.
- 2.2 There were various views on the necessity and feasibility, of reducing specific chemicals. Only tobacco specific nitrosamines are unique to tobacco anyway and a moving target syndrome was anticipated: Compounds would always be added to the list.
- 2.3 The more pragmatic approach of reducing tar [probably at constant nicotine level] was discussed. This approach had been specifically requested by regulatory authorities (e.g. U.S.A., U.K.), whereas there was equivocal advice on reduction of specific chemicals.

The approach was also consistent with effects of nicotine such as the apparent negative association of smoking with Alzheimer's Disease, Parkinson's Disease, etc.

It was agreed that this approach complimented the approach of Project EMN.

- 2.4 With regard to the four research areas, it was agreed that the first step was an on-going appraisal of the scientific literature as discussed in "Rationale for R&D", A.L. Heard, 29.10.85. Resource in this area was being increased with the forthcoming appointment of a Senior Scientific Adviser in BATCo, Millbank.

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The Scientific Research Group (S.R.G.) was charged with appraising the literature and, if necessary, organizing further work. It was noted however that a considerable amount of work was already going on in all four areas.

In detail there was discussion as to whether the concept of a "threshold" was useful in terms of chemicals in smoke, the confused status of biological tests, the inherent limitations of epidemiology and the current status of work on disease mechanisms and role of vitamins etc.

The S.R.G. would be asked to examine if sufficient work was being carried out to meet the requirements of the project.

2.5 It was agreed that time scales could not be set realistically because of the uncertain nature of scientific research. However, all necessary resources would be provided.

2.6 It was also agreed that the S.R.G. would consider the implications of the tar reduction programme in terms of necessary research. In any case the next meeting of the S.R.G. (Montreal, August 1986) was already scheduled to discuss nicotine in detail.

2.7 The matter would be further discussed at the 1986 Research Conference (Sydney, September 1986) and at a projected meeting of BAT No. 1's to be held in due course.

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Comments on Project EMN

Author: Dr. F.J.C. Roe

Date: 21st July, 1986

1. It is nice once more to see optimism and vigour stemming from the Tobacco Industry in relation to smoking and health problems! These characteristics more or less disappeared from the UK scene after the failure of tobacco substitutes. The question is, is there now a firm basis on which their revival is justified?
2. In the 1950's and 1960's it was not unreasonable to postulate that the carcinogenicity of smoke and, perhaps, too the emphysema-enhancing and heart disease-enhancing properties of smoke, are due to one or more smoke ingredients which, if identified, might be eliminatable by modification in tobacco or cigarette design. The fact that pipe-smoking is relatively much safer than cigarette smoking has always given credence to this approach, although, alas, the Tobacco Industry has never considered any smoking product that did not look rather like a cigarette to be commercially viable.
3. The fact is that a generation of research on fractionating smoke and on comparing the effects of different tobaccos and cigarette designs has led to no breakthrough in relation to any smoking-associated disease that could not be as easily achieved by simple reduction in tar delivery. A severe constraint has always been the acceptability of the product and manufacturers know very well that there is a point in tar and nicotine reduction below which most smokers are not prepared to go.

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4. In the case of carcinogens, smoke contains not just one carcinogen but a galaxy of them. Furthermore it is, at present, inconceivable that carcinogens would not be produced during the pyrolysis of any organic material.

Elimination of carcinogens does not therefore appear to be feasible. The same is seemingly true for the irritants (especially oxides of nitrogen) responsible for non-neoplastic lung-disease (emphysema and chronic bronchitis). In the case of heart disease, carbon monoxide and nicotine have received most attention but in neither case has a causal relationship been unequivocally demonstrated. In any event, it is difficult to see how either of these smoke constituents could be eliminated were it found to be the culprit. At present, therefore, it must be concluded that the "E" of "EMN" is no more than a pious hope.

5. The scope for further modification is presently limited by three considerations, (i) public resistance to tasteless low-nicotine delivery smoke, (ii) by the resistance of the Tobacco Industry to depart radically from conventional cigarette-type products, and (iii) by the unlikelihood that a completely carcinogen and irritant-free smoke could be produced.
6. This leaves for consideration the possibility of neutralisation, e.g. by the administration of vitamins such as Vitamin A and/or C to smokers. This approach has not yet been fully or adequately explored. However, in the light of what is known about mechanisms of carcinogenesis and about the causation of emphysema it would be surprising if any means of completely neutralising the adverse effects of smoke on the risk of

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these diseases were found. I do not doubt that reduced food intake generally could largely eliminate heart-disease risk. However, unfortunately people are even less willing to cut down on eating than they are to give up smoking.

7. In my view, therefore, it is most unlikely that within the scope of acceptable cigarette design, it will prove possible further to reduce substantially the risk of smoking associated disease. To achieve this the Industry will have to step outside the constraints dictated by conventional cigarette design and contemporary smoking habits (e.g. in the direction of a return to pipe-smoking).
8. Reluctantly, therefore, I have to conclude that the paper on Project EMN which has been sent to me has the features of a light-weight patchwork quilt of 1960 design. I am sorry to have spilt tea on it!

FJCR
21.7.86

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PROJECT EMN

COMMENTS ON PROJECT BY IMPERIAL TOBACCO LTD., CANADA.

Stated Objective

1. "The Study of Tobacco Products for the purpose of alleviating Perceived Health Risks."

The course of action: Design a programme that takes us from our present programme of gross reduction of toxic smoke components to a program of selective reduction of specific tobacco smoke components to reduce the specific toxicity of tobacco smoke. This programme will be based on the recommendations of medical and scientific experts.

Fundamental research is not, in itself, an objective; it is a strategy.

It is a selected course of action which affords the most support to the achievement of an objective.

2. The above project is seen in three phases:

Eliminate E
Modify M
Neutralize N

and relates to the views of other people in respect of modifications which they think should be made to a cigarette to reduce perceived health risks.

3. In more detail the project proposed is seen as follows:

Identify the Undesirables
↓
Eliminate the Undesirables
↓
Modify the Cigarette
↓
Neutralize

Comments

4. The project rationale assumes that there is a reasonably solid scientific background on which to proceed, regardless of judgements of medical authorities on the directions in which to proceed. It is proposed first of all to examine the scientific basis for action.

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5. There is a degree of unanimity between regulatory authorities on compounds in smoke which they identify as undesirable, and which do not appear to relate to consumer satisfaction. While we consider their role in cigarette smoke to be unclear, we can react or reasonably anticipate the views of regulatory authorities by reducing or eliminating these compounds from smoke. In practice, elimination of materials from smoke produced in a combustion process is practically impossible, although reductions (of varying amounts) may be an attainable objective.
6. However, there is not likely to be any consensus view on threshold levels other than the view that it should be zero, and notwithstanding para. 5 above, this is the most obvious target.
7. It will be the role of the Scientific Research Group (S.R.G.) to maintain an on-going appraisal of the scientific literature. This could include some assessment of compounds which regulatory bodies have identified. The next stage would be a programme of research based on cigarette design, combustion and filter research, designed to reduce as far as practical, identified compounds. This could be a huge amount of work, although some existing projects fall within this area.
8. In relation to reductions in specific toxicity, ranking of cigarette types in different biological tests varies according to the test. As the relevance/importance of the tests to real life situations (if any) is arguable, there is not yet a firm basis for using such tests to direct the project. This position could change, particularly if work in molecular biology, for example, clarified the relevance of particular tests.
9. The scientific basis for a "neutralization" project is even less secure than the interpretation of results from biological testing, assuming for example that it relates to the claimed effects of ingestion of Vitamin A etc. In any event this area would impinge on industries other than tobacco.
10. What is currently feasible:

Some response, in chemical terms, to the views of regulatory authorities.

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A check on the effect of any such chemically driven changes by generally accredited short term biological tests. As a starter, to determine ultimate biological end points, using existing tests the activity of the following four tobacco related products might be worth evaluating.

1. High tar plain cigarette.
2. Modern low tar filter cigarette. *← 2.000*
3. Combustible cellulose device with added nicotine, possible burn additives.
? NSM + nicotine. *Constant nicotine*
4. Favor.

11. This has broad similarities with the stated objectives of project EMN (first two parts) although these comments indicate that the project should be called IME (Identify, Modify, Eliminate).

*Read
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