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ENVIRONMENTAL TOBACCO SMOKE (ETS) - THE SCIENTIFIC ISSUES

(Draft for Discussion in Preparation of the Washington Meeting.)

INTRODUCTION:

This paper has the objective of outlining the basic areas of scientific controversy in the passive smoking field, to sketch possible experimental approaches for their resolution, and to list independent scientists who might be capable of carrying out some of the required work.

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DESCRIPTION OF AREAS OF RESEARCH INTERESTS:

1. ANALYTICAL CHEMISTRY OF ETS.

The basic objective of such research is to determine, in qualitative and quantitative terms, the composition of ETS as a function of the numbers of cigarettes smoked per unit volume, as well as a function of time, both in laboratory conditions and in the field, in order to have reliable reference or baseline values available describing ETS in realistic terms.

Concerted research in this area is ongoing. Both the VdC and TAC are presently pursuing such research and practical results are continuously being gathered. Such research has to be widened in scope and also in geographic terms, including countries other than the BRD and the UK.

The compounds for which measuring techniques have been developed or adapted for ETS conditions include nicotine, carbon monoxide, particle mass, particle count and size distribution, nitric oxide, nitrogen dioxide, ammonia, amines, nitrosamines, aldehydes, and phenols.

By spring 1985 sufficient data should have become available to enable a constructive approach of university laboratories or other scientific institutions who work in the field of atmospheric contamination. A possible list of names should be compiled for individual countries in collaboration with local industry scientists.

2. DOSIMETRY, i.e. HUMAN UP-TAKE STUDIES.

ETS, being a changeable mixture both over time and in dependence of environmental conditions, cannot be described as if it were chemically a defined substance. Dosimetric studies must therefore relate to individual

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constituents and are not translatable across the board into "cigarette equivalents" or "tar equivalents" in relation to mainstream smoke.

Basic work is being carried out presently, especially in the BRD and the USA. The basic ratio for such research is that without the knowledge of dosimetry, exact epidemiology cannot be performed. Results of dosimetric studies are at least necessary to confirm the results of questionnaires used in epidemiology. Whilst methods for the determination of nicotine and its metabolite cotinine using immunologic principles have been developed to a level of sensitivity and precision, which make them in principle applicable to ETS exposure, no valid methods are available for most other ETS constituents except for carbon monoxide.

As the danger exists that sloppy work in this area could be published and cause immeasurable harm, serious independent work must be supported in order to provide a proper scientific perspective on the possibilities for obtaining valid dosimetry results for selected ETS constituents. The scientific difficulties are substantial which means that no immediate results can be expected to be forthcoming. However, scientists working in this area could refute, based on their practical experience, any published data which were obtained by unsuitable methodology.

3. TOXICOLOGY, i.e. ANIMAL OR CELL BIOLOGY WORK.

In order to be able to put results of dosimetric studies into perspective, i.e. to deduce any conclusions with regard to effects over a wider dose range, model systems have to be exposed to individual ETS constituents in a dose range embracing the values obtained in human up-take studies. Such model systems could consist of experimental

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animals, cell cultures or combined homogenized organ / bacterial cell systems. Dose effect curves are of such importance because of the controversy over low dose effects. For many compounds there exists a no-effect dose range at the very lower end of the exposure curve. Wherever such threshold values exist, their determination in several biologic test systems is necessary in order to arrive at a considered opinion as to their applicability for the human situation.

The application route is a factor which is of importance when using animal models. Although in many instances there are route-independent target organs, the inhalation route will be required for ETS studies. In order to quantify data, the determination of the inhalation dose will necessitate comparative measurements with other parenteral routes.

As for dosimetric studies in humans, the animal work needs a solid base of chemical data on ETS. However, selected projects could already be initiated in this field.

4. EPIDEMIOLOGY.

Published data in literature so far have relied almost exclusively on circumstantial evidence for dose estimation. Instead of relying on measurements, assumptions were made along the lines that, for example, a woman married to a nonsmoker would be less exposed to ETS than a woman married to a smoker. Similar considerations were made with regard to smoking parents, smoking colleagues at work, etc. In fact, it was concluded by experts last April at the Vienna Symposium that, as long as there are no numerically quantifiable data on received ETS dose available, far reaching conclusions on any risk from ETS exposure cannot be drawn.

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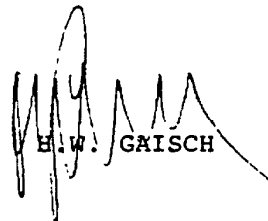
Epidemiologic studies searching for possible effects of ETS exposure - which, if existent, must be extremely weak - must have a solid experimental back-up by chemists, physicists and toxicologists in order to be able to exclude other overriding stronger influences.

At present, the methodologies for such a concerted support do not exist. However, it is important that some epidemiologists enter the field by doing pilot work in order to be able to refute the work of sloppy authors who overstate the implications of their findings.

CONCLUSIONS:

The scientists of the "Passive Smoking Assessment Group" (PSAG) should start the process of short-listing possible independent scientists in collaboration with local industry scientists. Once such a list, which is by necessity open-ended, has been established, the first contacts could be made. The process of establishing and deepening such contacts is fairly delicate and the industry scientists who are charged to do this must be given a fair amount of freedom of approach. Before any project is finalised and approved, a detailed evaluation has to be made by the PASG and each individual project must be approved by the INFOTAB hierarchy.

Funds should be channeled through intermediates who have the responsibility of ensuring the appropriate use. Typically this will be a university trust or a firm of accountants specialising in such matter.


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