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Papers

Lead

KE 0019416

MEMORANDUM

To: George Roush, Jr., M.D.

From: Robert A. Kehoe, M.D.

ON THE STEPS BY WHICH TETRAMETHYLLEAD CAME TO BE INTRODUCED
INTO MOTOR GASOLINE AS A SUBSTITUTE IN PART OR WHOLE FOR TETRAETHYLLEAD

In view of the greater volatility of tetramethyllead, as compared with tetraethyllead, the use of the former compound of lead was considered, at an early date, to be an advantageous possibility, largely because of the likelihood of the more uniform distribution of the more volatile lead compound among the several cylinders of an internal combustion engine.

After the examination of the toxicity of this compound, along with certain other organo-lead compounds, by Willard Machle, M.D., in the Kettering Laboratory in 1936, the opinion was expressed by the Laboratory that the risk which would be incurred by Ethyl Corporation in the commercial exploitation of this compound was probably excessive. This opinion was accepted and the matter was dropped.

Years later, research on automotive engines in the laboratories of a number of oil companies resulted in the revival of interest in the potentialities of tetramethyllead as an antiknock agent. This culminated, in 1959, in the decision by one of the oil companies to make use of tetramethyllead in certain of their gasolines, unless its use would, in fact, give rise to a significant degree of danger in the distribution or the use of gasoline containing tetramethyllead. (There were, of course, other potential hazards in association with the production and handling of tetramethyllead, but it was considered, on the basis of prior experience with tetraethyllead, that those associated with the manufacture and transportation of an antiknock fluid containing tetramethyllead could be dealt with effectively. Public and occupational hazards due to tetramethyllead in commercial gasolines, on

(The other hand, could hardly be regarded as amenable to satisfactory control.)

It was fully recognized, in the Kettering Laboratory, that the opinion expressed in 1936, that the use of tetramethyllead would probably be hazardous, was tentative, in that the matter had not been put to a test. Meanwhile, with the experience of the intervening years, methods of environmental and physiological observation had been developed to a point that made it possible to determine the potentialities of exposure to and absorption of lead in advance of any danger of lead intoxication. Accordingly, it was proposed by the Laboratory that a miniature set of operations, similar in type to those of conventional commercial operations, from the manufacture of tetramethyllead through all of the steps that come to an end with the combustion of gasoline containing tetramethyllead in the engine and the discharge of the products of combustion from the tailpipe of automobiles, should be instituted, under conditions which would be compatible with the monitoring of the several types of environment, as well as the personnel whose activities would be carried out within such types of environment.

It was also foreseen and made clear to the technical and administrative representatives of the industries involved, that a field investigation of a crucial type would have to be carried out over an appropriate period of time, should the test of the operations in miniature fail to reveal the existence of any actual hazard due to the use of tetramethyllead.

Since, by this time, the technical advantages associated with the use of tetramethyllead appeared to justify the trouble and expense which would be involved in the proposed investigations, the companies concerned with the production of tetramethyllead, with the oil company directly involved in the exploitation of the gasoline, entered into a cooperative arrangement for supplying the preparations, assistance and funds that would enable the staff of the Kettering Laboratory to carry out its part of the investigative program to its own satisfaction.

Meanwhile, appropriate representatives of the Public Health Service, with whom, for many years (of changing personnel), Robert A. Kehoe, M.D., Director of Kettering Laboratory, had maintained a full exchange of information pertinent to problems of occupational and public health in relation to tetraethyllead, were informed of these developments, and given the opportunity to offer any criticism or advice which might to them seem in the public interest.

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It is necessary, at this point, to call attention to the fact that the relationship of the Public Health Service to the industrial organizations concerned with the production and distribution of lead-containing antiknock formulations, as developed in 1926 with Ethyl Corporation and continued, with some attenuation, after the entry of other industrial organizations into these fields of operation, had undergone a radical change on or about the year 1959. The original relationship, initiated by Surgeon General Hugh Cummings, of the Public Health Service, and Earle W. Webb, President of Ethyl Corporation (at that time, Ethyl Gasoline Corporation), was that of an agreement of gentlemen, acknowledged partially, as a matter of record, in various publications of the Public Health Service, whereby Ethyl Corporation undertook to inaugurate and sponsor the investigative work required in the realms of occupational and public health to establish the facts concerning the potential or actual hazards involved in the business, and to develop and apply appropriate safeguards against such hazards. The Corporation further obligated itself, in this manner, to furnish full information to the Public Health Service in all matters concerned with human health and hazards thereto, as such information came to light out of experience and research, and to be guided in such matters by the advice of the Service. These obligations were adhered to faithfully by the Corporation.

A reexamination of the legal and official position of the Public Health Service in this relationship took place in association with or following the deliberations of the Public Health Service concerning the increase in the maximum concentration of tetraethyllead from 3 ml. to 4 ml. per American gallon, in 1959. No objection to the latter proposal by the industry was raised by the Surgeon General of the Public Health Service, after a formal inquiry into the situation had been made and reported by a special ad hoc committee of experts. Shortly thereafter, however, it was made clear to the industry that a decision had been arrived at, on legal advice, that the "gentlemen's agreement" of 1926 had no legal authorization, and that it could no longer be regarded as a basis for any continuing regulation of the industry in matters of health and hygiene by the Public Health Service. Since that time, the procedure on the part of the industry, in accordance with the advice of the Service, has been that of informing the Service, voluntarily and in advance, concerning its proposed action in relevant matters, whereupon the Service may choose to give expression to its views for such use as they may be to the industry. The latter have neither a permissive nor prohibitory character, since the Service has no formal authority in either direction. The industry takes such action as it may choose, in matters that are not subject to statutory regulation, and accepts the full responsibility for its own action.*

* The documentation of these statements is to be found in a special file maintained by the author of this memorandum, containing all of the relevant correspondence with representatives of the Public Health Service since 1926, during which period he has acted as professional adviser to the industry and as its intermediary in consultation with the appropriate representatives of the Service. During portions of this period he has been a formally appointed consultant to one or another branches of the Public Health Service, and now serves in that capacity to the Occupational Health Program. He did not contend for the views of the industry, therefore, but rather presented the facts as he saw them, in consultation with his peers in the Public Health Service.

As stated above, when faced with the policy of the Public Health Service described in the foregoing paragraphs, and with an important departure of the organo-lead antiknock industry from its previous technical and commercial practices in the offing, the decision was arrived at unhesitatingly, to acquaint the Service with all of the facts, including the proposed program of investigation, and to seek an exchange of views on all aspects of the matter. This was done and assurances were given and received as to the fullness and freedom of such exchanges, in the public interest and for scientific purposes. The policy of the Public Health Service, however, with respect to its lack of authority and responsibility, was reaffirmed.

In May of 1959, the preliminary experiment involving the use of tetramethyllead was initiated in San Francisco, California and was completed some months later, as described in detail in a Report of the Kettering Laboratory, dated November 10, 1959 and entitled "An Investigation of the Potential Hazards of Exposure to Lead Associated with the Handling and Use of Gasoline Containing an Antiknock Fluid in Which Tetramethyl Lead is Substituted for Tetraethyl Lead." In this report, the conclusion was arrived at that "there appears to be no hygienic reason against the use of tetramethyllead", but it continued with the reminder that field investigations would be required, from time to time, in connection with the commercial distribution and use of gasoline containing tetramethyllead, to determine the influence of time and the scope of the operations upon the outcome. This report was furnished to appropriate representatives of the U.S. Public Health Service.

In 1960 and 1961, a field investigation was carried out by members of the staff of the Kettering Laboratory in California, with the assistance of technical personnel of certain local industrial organizations, in which the extent, if any, of the occupational absorption of lead, and the effects, if any, of such absorption,

on the part of personnel engaged in all of the commercial operations concerned in the production and distribution of gasoline containing tetramethyllead, were sought out by appropriate methods. An interim report of these observations was issued on March 23, 1961, and a final report, following the completion of the investigation, entitled, "On the Potential Hazard Associated with the Introduction of Tetramethyllead as an Antiknock Agent into Commercial Motor Gasoline, with Respect to the Absorption of Lead by the Handlers of Such Gasoline," was issued on July 10, 1962.

Suffice it here merely to cite the fact that the field investigation failed to yield any evidence of the actual existence of any hazard from the absorption of lead imposed upon any of the personnel engaged in operations concerned with the preparation, distribution and handling of gasoline containing tetramethyllead. The reports issued in evidence of the correctness of this statement, have been made available to personnel in the U.S. Public Health Service, to representatives of the industries concerned, to other health agencies in this and other countries, and to certain other colleagues and scientists on requests addressed to the Kettering Laboratory.

There being no hygienic reason to discriminate between tetraethyllead and tetramethyllead as antiknock agents in commercial gasolines, no special regulations have been proposed or promulgated. Certain general precautionary practices, having to do in principle with those long in use in connection with gasolines containing tetraethyllead, have been applied to gasolines containing tetramethyllead. These too have been put into use with the full knowledge of the U.S. Public Health Service. Nothing has occurred since 1960 to suggest that such self-imposed regulations are unsatisfactory or inadequate.

September 21, 1967