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FDA

From the desk of
C. W. Jones

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Attached are the "hand-outs"
from the FDA press conference
on Sept. 29 as sent in by
Sam Pickard.

EVJ

EXHIBIT
WBP M-66

MON-MT-008649

ready → STATEMENT BY CHARLES C. EDWARDS, M.D.

PCB PRESS BRIEFING
SEPTEMBER 29, 1971

We have called this briefing to try to help establish perspective on PCB's, the extent of their presence in the food supply, the implication this has for human health and what the government is doing to define and control the problem generally.

There is today considerable public and some obvious press confusion. Some of this confusion is due to the intense complexity of the PCB issue and to deficient knowledge about the substances in terms of effect on human health.

The confusion is compounded by a few alarmists seeking headlines. Their efforts have in some few cases been aided and abetted by unbalanced reporting.

Public confusion has created public alarm and a feeling of still another crises in the food supply.

I know the confusion is unnecessary and I believe the alarm is greater than the facts will justify.

And this is the reason we have asked you here -- to try to give you the facts that we have, to share with you the limits of our knowledge, to tell you what we are doing with the information we have, what we are doing to get more information and, finally, to answer any questions you may have.

The PCB problem is one which cannot be easily defined. This family of industrial chemicals has been used in countless useful and beneficial ways for more than 40 years. Nevertheless, they have no place in the food

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supply. FDA, other agencies of government, and industry itself have been looking at PCB's since at least 1966 to try to keep the chemical out of foods and to try to assess what if anything it means if it should be found in food.

We still have as many questions as answers but we do have some answers. We do know that as a toxic substance PCB's are a potential but not immediate health hazard. We do know that its background level in the environment is not high. But we do not know how long term exposure to PCB might effect human health and we cannot yet explain the inconsistent presence of the chemicals in certain areas of the environment.

We do know there are certain strong reasons for continued use of these chemicals. For example they have important flame resistant properties and properly used, directly assist government and industry in protecting the consumer against fire. We do not know if a requirement for substitute chemicals in some cases might not prove more of a health threat than PCB's.

In recent months we have been faced with PCB adulteration of foods from an industrial accident in North Carolina, from recycled paper packaging and from untraceable environmental causes.

Given the length and variety of uses and given the present intensity of the present search we can be confident that other problems will be found and reported in the weeks and months ahead.

But the overall problem is not new to FDA or to government. FDA developed the technology to identify and measure PCB content in foods and other substances. The Agency at least three years ago established a 5 ppm guideline for PCB in fish. The Agency has consistently backstopped USDA in dealing with the problem whenever it occurred in the poultry industry.

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The PCB issue, like NTA and mercury for example, points up the need for Congressional passage of the Administration's Toxic Substances Control Bill. The ultimate solution to the PCB problem, lies, at least in part, in restricting uses to those places where the substances can be safely and beneficially employed. Good progress is being made toward this goal.

But the Toxic Substances Control Bill would clarify and strengthen our authority in this area. Furthermore, it seems clear we will have more PCB "incidents" until a system for pre-testing of such chemicals is established. The Toxic Substances Bill would establish such a system. In fact, the Council on Environmental Quality, in its report of last April entitled "Toxic Substances" used PCB's as one of the examples of substances which the proposed legislation is designed to control.

On another tack I want to remind you that the FDA in full recognition of the fact that the problem of PCB's is broader than any single agency of government, recently took the lead in calling together six major Agencies of the Federal Government. The result was establishment September 1, 1971 of an Inter-Departmental Task Force to coordinate government activities, to facilitate the exchange of information and to do all else possible to bring government resources to bear in defining and dealing with the problem as needed.

I urge your additional attention to the joint press release issued on September 5 about this Task Force. Copies are available.

In a moment I want to ask Deputy FDA Commissioner Grant to give specific citations of actions that FDA and others have taken to meet and reduce health dangers or unwanted adulterations from PCB's.

Before I do, however, I want to make three further and very brief points:

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1. We are taking specific, adequate and positive steps to deal with whatever problem or potential problem that PCB's are likely to pose to human health.

2. We reject the need and in fact the feasibility as some have proposed for an outright ban on the substances. Although the use of PCB's requires control, an outright ban is not feasible and would not be in the best interest of the consumer.

3. We further reject the idea that crisis headlines and demands for national health alerts are justified or needed to meet the situation as we know it today. Science does not support such actions and we in FDA will continue to abide by the dictates of science in making regulatory judgments in behalf of the American consumer.

Thank You---

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*Read
by Grant.*

September 29, 1971

PCB ACTION SUMMARY

To summarize this chronology, I offer the following:

1. Based on the levels of PCBs we have found in our scientific evaluation of the health hazard, except for accident-type situations, we do not have an imminent health hazard problem, but PCBs are a potential hazard.
2. We are taking steps to cut off further introduction of PCBs into the food supply and to reduce the current low levels of PCBs as a food contaminant. We want to remove all PCBs from food from environmental or any other sources. By doing this we will eliminate the potential problem.
3. We need more scientific information on PCBs. The Government is working on this need.
4. We need more information on the extent of PCBs as an environmental contaminant and the extent of PCBs in the food supply. We are collecting such information.
5. PCBs serve many beneficial purposes.

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6. We have been monitoring the food supply for PCBs for some time and have developed reliable procedures for doing so.

7. We have acted specifically where action was warranted, and we have taken steps to deal with the long-range problem.

8. FDA developed a scientific analytical methodology to enable PCBs to be found in containers as well as food.

9. We have taken steps in concert with other agencies to protect the public.

10. Except for isolated incidents involving fish, almost all of the high levels of PCBs found have been associated with accidents, which we are working to prevent. We have set appropriate guidelines for regulatory and control actions.

11. We have stepped up our surveillance of the food supply to detect PCBs within our limited resources.

12. We have a coordinated government effort through an inter-agency task force under the direction of the Office of Science and Technology and the Council on Environmental Quality to deal with the problem.

13. We are bringing together the best scientists and data in the country to deal with the problem.

*major
scientific
meeting - soon*

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14. We have met with the industries involved to deal with the problem. The following actions have been taken:

a. The Monsanto Chemical Co., the primary domestic supplier of PCBs, is only selling the compounds now for transformer, capacitor and non-food heat exchange uses.

b. PCBs are not now being used in the National Cash Register Company's carbon paper, but there are large quantities ^{of carbonless carbon paper containing PCBs} in office files throughout the country.

c. The NCR carbonless carbon paper is not now being used in recycled paper intended for food packaging.

d. Over and above FDA's increased surveillance, the food industry is now surveying its own plants and its products to be certain the PCBs are not being used. The food industry has been alerted to the need to avoid paper containers with PCBs.

We do not believe

15. In summary, PCBs are not an imminent hazard and the Government with full cooperation from the private sector is taking steps to eliminate the potential hazard.

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FOOD AND DRUG ADMINISTRATION

September 29, 1971

- 1966 Soren Jensen reported PCB in Swedish fish and wildlife.
- 1967 G. Widmarck published "IUPAC Commission of Methods of Pesticides Analysis: Possible Interference by Chlorinated Biphenyls."
- This article began FDA methods development program to separate polychlorinated biphenyls from chlorinated pesticides encountered in regulatory analysis.
- Feb. 24, 1969 Dr. Robert W. Risebrough widely quoted from San Francisco Chronicle Story warning of PCB in eco-system.
- March 7, 1969 Associate Commissioner for Science and Deputy Associate Commissioner for Compliance asked Bureau of Science to evaluate foods sampled for pesticides for evidence of PCB. None was indicated except in some fish from the great lakes.
- March 10-14, 1969 District pesticide experts were given all of the analytical information concerning PCB and told to be aware of the possibility of its presence in foods. (Pesticide Analytical Workshop 3-10/14-69.
- June & July 1969 PCB was identified as a contaminant of many fish analyzed as part of Injunctive proceedings against the City Smoke Fish Co. of Detroit, Michigan. These fish also contained DDT above 5 parts/million.
- The firm was enjoined by U. S. District Court.
- July 1, 1969 Eleven page Bulletin was issued to all field districts regarding PCB in fish and outlining instruction how to separate PCB from chlorinated pesticides. Information on any results of apparent PCB findings or unidentified organohalogen residues was to be reported.
- Sept. 13, 1969 Baltimore District Office reported PCB in West Virginia Milk. This series of samples was traced to use of Aroclor Oil as solvent for pesticide spray. Grade A milk shippers involved were taken off production by the State.

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Dec. 16, 1969 Regulatory Action at 0.2 ppm (whole milk basis) was established.

Jan. 6, 1970 PCB analysis included in Total Diet Study.

Feb. 3, 1970 Regulatory Action at 5 ppm in edible flesh of fish established.

Mar. 24, 1970 State of Ohio advised FDA they had a problem in milk resulting from Arochlor containing silo sealant. State was told FDA would initiate Federal seizure at 0.2 ppm (whole milk). State handled the problem and dumped an unknown quantity of milk.

Aug. 7, 1970 Fish near effluent Annison Plant Monsanto found to contain PCB. Results were reported to State (these were recreational fish).

Nov. 10, 1970 Formal program for PCB in raw agricultural commodities issued. To date 15,000 samples analyzed with 279 "random" PCB results reported.

Jan. 29, 1970 New York State Poultry. Feed ration contained ground bread cartons and wrappers. PCB in feed may have originated from this source but is not confirmed at this time. Investigation continuing.

Action level 5 ppm PCB in poultry established.

July 16, 1971 Leakage of heat exchange of fluid caused contamination of pasteurized fish meal which in turn was fed as a ration to chickens and catfish.

Aug. 1971 Action level 0.5 ppm established for eggs. 5 ppm reaffirmed for poultry.

Aug. 9, 1971 PCB reported in turkeys in Minnesota. FDA investigation could not determine that feed or its constituents was cause. Investigation continuing.

Aug. 11, 1971 Seizure recommendation 75,000 eggs Norfolk, Va. (follow-up Wilmington Terminal). Grain and cereal composite of total diet study found to contain PCB at 0.4 parts/million level. Packaging for shredded wheat component was source of the contamination. Packaging Survey initiated by home district CIN-DO. Highest level 433 ppm found in greyboard.

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- Aug. 12, 1971 Cargill Inc., Pensacola, Fla. Heat exchange leak of Therminal 55. Not PCB related. 1.6 ppm PCB may be environmentally in fish meal. Investigation continuing.
- Aug. 23, 1971 National Bi-Products, Mason City, Ill. Meat scrap meal may have been contaminated at 1 ppm level. Material was recalled.
- Sep. 1, 1971 Meeting of Interagency Group with Commissioner to become familiar with and organize to solve many of environmental problems associated with Aroclors.
- Sep. 3, 1971 Conference with American Paper Institute to find out what information they could give about recycling. It was reported NCR had discontinued PCB in copy paper as of June 1, 1971.
- Sep. 8, 1971 Meeting with Monsanto Chemical Company. - Company told FDA PCB would be limited to essential closed system uses with no use in food or feed plants.
- Sep. 14, 1971 Meeting with Food Manufacturers to inform them of PCB risks in greyboard packaging.
- Sep. 14, 1971 Compliance Program issued to Regional and Field Offices to survey 15 food commodity categories for PCB.

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